Sustainability in MedTech Design. Methods, Tools and Practice

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Edited by Amina Pereno

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Introduction

Amina Pereno, *Politecnico di Torino*

Introduction

Health has always been at the heart of our societies' interests, although it has taken on different connotations over the centuries. From the concept of being the simple absence or curing of disease, we are moving towards an idea of well-being and quality of life as a priority in an increasingly ageing population. In either case, whether it is to fight diseases or ensure healthy ageing, we need effective strategies and physical goods. Over the centuries, the healthcare sector has built up its own unique collection of drugs, products and devices that are essential for daily routines as well as emergency medical procedures. This system of goods that fills our healthcare facilities, but also and even more so, our homes, does not come without side effects. Like any other manufacturing sector, these include resource consumption, energy demand, waste production, but healthcare has peculiarities that make the dark side of the system particularly critical, from the huge demand for chemicals and radioactive products, through the release of drugs into the environment, to the immense production of special waste requiring dedicated management.

For years, it seemed to be just a small - economic and environmental - price to pay in order to ensure the health of our societies. Over the past 25 years, people have gradually become aware that this price is not cheap and above all has a direct and negative effect on our health. The same system that fights cancer produces tons of carcinogens with devastating effects on people and the environment. The turning point was precisely that human health cannot be dissociated from the planet's health.

How to reimagine two aspects that for decades have progressed on separate tracks?
And where should we begin to rethink the products that make up our healthcare systems?

Sustainable healthcare is an increasingly debated concept that is fascinating, forward-looking, and necessary, yet sometimes still too theoretical. The complexity of rules and laws in a sector such as MedTech, combined with the incredible complexity of patient safety requirements, makes a sustainable transition more challenging than in any other sector.
Yet small tangible steps are possible, starting from the product but with an eye to the system, because the complexity of MedTech makes simple 'green' device logic useless. It is necessary to start small, from the bottom, but with an overall vision of the sector and its sustainability goals.
To achieve this, the first step is education. Engineers, designers and experienced MedTech professionals cannot be expected to suddenly incorporate sustainable strategies and criteria into their design process. What strategies? By what means? They should first understand what sustainable design means, what circular healthcare is all about, and how they can define practical tools for their specific MedTech solutions.

This book is based on these assumptions and aims to provide professionals working or aspiring to work in MedTech with an overview of the sector from a sustainability perspective (Chapters 1 and 2). Then, the publication provides some practical concepts and guidelines for sustainable MedTech product development, considering products, services and packaging (Chapter 3). It then moves on to explore governance and business strategies to include sustainability at the company-system level, also delving into the concept of systemic design (Chapter 4). Finally, the conclusions highlight the most promising trends in sustainable MedTech, which designers and managers should take into account in the medium and long term.

While the book is designed as a stand-alone publication, it is also the result, and an integral part, of the 'Sustainability in MedTech Design' online training programme, which was developed within the SysteMA project, funded by EIT Manufacturing (id. 22111). The training is available on the Skills.move platform (www.skillsmove.eu), which offers training courses for manufacturing practitioners.

1

Design for better health and care: towards sustainable healthcare

Amina Pereno, *Politecnico di Torino*

1.1
Strategies and balances in the healthcare sector

Health systems aim to respond to the population's health needs by providing services that help preserve and restore the health and well-being of people. Today, health systems worldwide face radical changes and common challenges in pursuing their mission. Firstly, massive cuts in public spending are driving the healthcare sector towards defragmentation: merging hospitals and healthcare facilities aims to increase efficiency by exploiting economies of scale to expand services while reducing costs. Innovations in the sector are therefore shifting the focus toward prevention and well-being, moving care outside of healthcare facilities, and putting people at the centre of their own care (Deloitte, 2016; 2022). New technologies play a key role in this process, optimising treatment procedures and improving the digital connection between hospitals, clinicians and patients. Secondly, an ageing population is putting pressure on healthcare systems, resulting in increased demand for care, services and technologies to prevent and treat non-communicable diseases and chronic conditions associated with old age. The number of people over 60 years of age is expected to double by 2050, from 727 million to nearly 1.6 billion (United Nations, 2022). Chronic non-communicable diseases accounted for 74% of deaths globally in 2019 (WHO Global Health Estimates, 2020) and today they represent more than 70% of healthcare expenditure in the United States and the European Union. All these challenges have been intensified by the COVID-19 outbreak, as it drastically increased the number of patients, engendered employee burnout and brought to light weaknesses in the sector related to workforce shortages, supply chain disruptions, equipment scarcity and outdated facilities.

This is leading the healthcare sector to play an increasingly significant role in our economies, now accounting for 10% of GDP and 8% of the total workforce in the European Union. The European Commission (2016) acknowledges "the need to make health systems sustainable by making them more effective, accessible and resilient". In the short term, policy measures are needed to ensure the population's health and long-term care. As a result, **interest in what is known as sustainable healthcare is steadily growing.** Albeit piecemeal, European countries are implementing new sustainability strategies for the healthcare sector, aiming to **increase the economic sustainability of their healthcare systems, reduce the sector's impact on the environment and promote a new social approach to the concepts of health and care.**

1.1.1 A new approach to healthcare

Although healthcare organisations started to grasp the close connection between environmental protection and patient care as early as the 1990s, sustainable healthcare issues have only really gained momentum in recent years. The recent evolution of approaches to the topic also reflects this trend. The first steps in the field of sustainable healthcare were guided by the principle of 'primum non nocere', addressing problems that, in the short term, seemed most critical and harmful to the health of the planet and, therefore, of people (see par. 3.2). While the replacement of chemical and pharmaceutical products with a high environmental impact, promotion of energy-efficient measures in healthcare facilities, and awareness-raising programmes among the medical professionals have produced significant results, they have provided **a piecemeal and one-off approach to a highly complex problem.** Therefore, today's research is shifting towards a more systemic approach to sustainable healthcare, which takes up the challenges of the circular economy (see par. 2.2) to rethink the sector as a whole. This involves proposing new design and economic models that consider healthcare processes and products in their technological, environmental and social complexity. Thus, new policy strategies are needed to foster connections between different sectors and to introduce new technological and organisational solutions originating in other sectors to the healthcare sector.

Economic sustainability is undoubtedly one of the key drivers. It has not only led to budgetary cuts to healthcare services (Clemens et al., 2014), but has also **encouraged qualitative approaches to savings** in terms of selective reduction and optimisation of resources, processes, and supplies (Evans, Hills and Orme, 2012). Besides the economic issues that call for higher efficiency and sustainability, **an increasing number of hospitals and health organisations have committed to reducing the adverse environmental effects of their operations on patients, staff, and communities,** becoming role models for the whole healthcare sector (Kaplan et al., 2012).

Although the evolution towards sustainable and circular healthcare is welcome and viable, there is still a fragmented and varied vision of sustainability issues in healthcare. Currently, hospital organisations and international associations are leading the way in the sustainable transition of the healthcare sector, while industry is embracing the change at a slower pace. There are also significant disparities between different countries, with healthcare systems in the UK, Sweden, the Netherlands, the United States, Canada and Australia being more advanced both in policy and innovation. In contrast, other countries in Europe and around the world show isolated good sustainable healthcare practices but lack a structural approach to the topic.

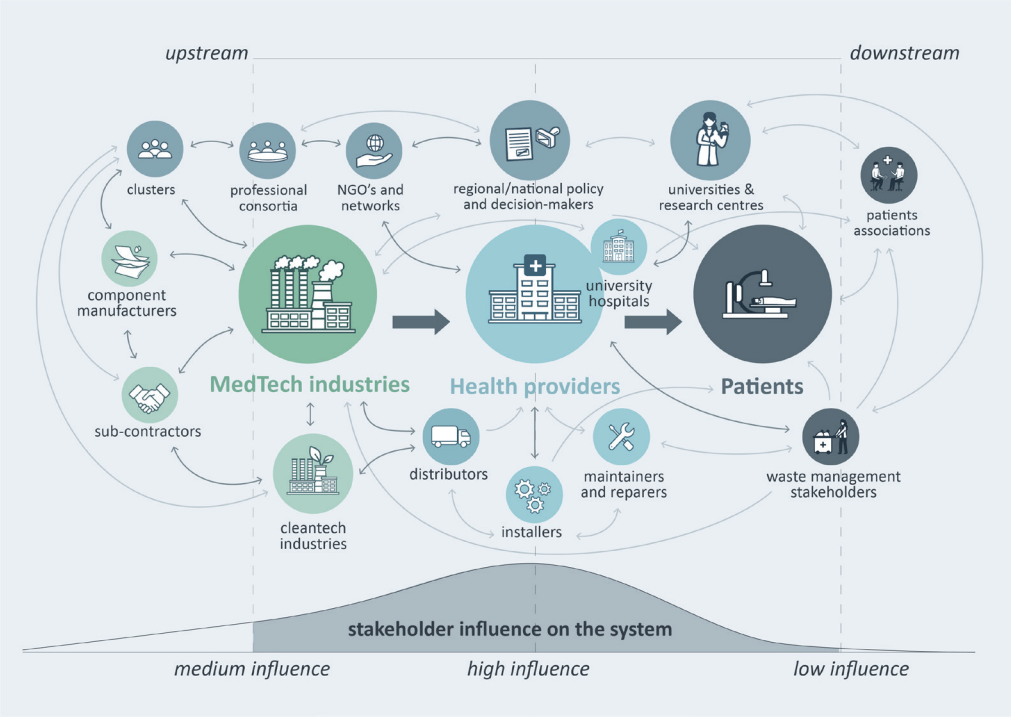

Figure 1.1: Graphical representation of the current healthcare value constellation and its stakeholders

1.1.2 Stakeholders' roles in the healthcare sector

Before exploring the interconnection between healthcare and sustainability and its main drivers, a comprehensive overview of the healthcare system is needed to share common definitions of key stakeholders.

First, the nature and complexity of this sector are best represented by the concept of **value constellation** (Normann and Ramirez, 1998), which goes beyond the idea of value chains to define the **complexity of a 'value creating system' in which different stakeholders from different sectors operate around healthcare delivery, generating a system of services, goods, design, and social value.**

Therefore, health stakeholders and their relationships comprise the healthcare value constellation, starting from the three main actors on which the constellation is based, namely **health industries, health providers, and patients** (Figure 1.1).
Each has a specific role that determines the relationships with other stakeholders and the influence on system choices, including those towards sustainability.

Health providers include public and private health organisations providing healthcare services. They have a strong influence on system sustainability as they procure and use products and services to deliver healthcare to patients. Procurement instruments demonstrate the importance of providers in demanding sustainable innovations and leading research in a specific direction. Health providers may be university hospitals that include local universities and scholars or may collaborate with academia through external collaborations. The heterogeneity of the internal structure—which combines management, healthcare and academic staff according to different and often parallel hierarchies—makes relationships with external stakeholders more complex. As a result, there may be communication failures and difficulties in establishing proper feedback loops on the use, management, and disposal of products and services.

Health industries include companies producing healthcare equipment and services, pharmaceuticals, biotechnology and other life sciences supplies. They have well-established networks of suppliers (component manufacturers and sub-contractors) and distributors built on trade relations. Collaborations on innovation topics, including sustainability, may occur but are not predominant or easy to implement.
A distribution network may include installers and maintainers who provide technical support to local health providers. Also, the presence of cleantech industries in the healthcare sector is rising as they provide new high-efficiency clean solutions to health providers, especially on sustainability priorities such as renewable energies, information technologies, green chemistry, lighting, and recycling.
However, a general lack of dialogue between industries and health providers is emerging. There is little feedback from the users who directly interact with products or services, especially in large public systems. At the same time, relations with patients can be more intense, as large companies often dialogue with patient associations (disease-specific patient organisations and national coalitions of patient groups) on problems related to specific diseases, but issues such as sustainability are hardly considered.

Patients are key stakeholders in the system, but their influence on changes in the sector is limited due to their fragmented nature and lack of purchasing power, particularly in public systems. The shift towards patient-centred care has already changed their role, moving towards self-care models, although they remain mostly passive within the system.

Other healthcare stakeholders interact with these three main actors through different channels and hierarchies.

The regional and national authorities have significant decision-making power over the value constellation, determining policies, strategies and public investments, also aimed at boosting sustainability in the sector. Depending on the national organisation, the degree of autonomy in procuring and delivering health services often varies. In some cases, regions centralise procurement, while in others, local health authorities have greater management discretion. Overall, regional and national authorities include policymakers, who set out policy agendas in the sector, and public decision-makers, who deal with technical and administrative issues and implement policy actions in the sector. Policy advisors, particularly at the national level, are key players in the healthcare sector, advising on policy programmes and initiatives and influencing policy decisions, especially on emerging priorities. Recently, we have been witnessing the creation of regional and national coalitions on cross-cutting topics, such as sustainable healthcare, in which different levels of public and private decision-makers engage in dialogue on how to align different strategies. This strengthens the possibility of dialogue with actors in ways that are new compared to the standards already in place.

Universities and research centres play a key role in driving innovation and have extensive knowledge in the field of environmental sustainability that could be transferred from other sectors to healthcare. However, their influence in the value constellation is currently limited, and their role is tied to one-to-one collaborations with companies, providers and other actors in the system.

NGOs and networks active in the healthcare sector range from scientific organisations, through foundations that address specific health challenges, to solidarity and international cooperation bodies. As regards sustainable healthcare, international NGOs were the first to deal with this topic and today gather hundreds of stakeholders. Therefore, NGOs and healthcare networks have an influential role in driving environmental strategies and promoting projects and campaigns at the international level.

Business and innovation clusters are established groups of industries, start-ups, and trade organisations that are active in the medical and life science sectors. They are key regional stakeholders as they often collaborate closely with regional authorities to support investments and establish sector strategies that can bring significant systemic innovation. Besides medical clusters, clusters from other fields, such as green chemistry or clean technologies, are also exploring sustainable and circular healthcare.

Professional consortia are self-governed organisations that gather representatives from a specific health-related value chain, such as pharmaceuticals or specific diseases, to promote innovations in governance mechanisms. Their involvement is essential for developing a long-term vision for the system.

Waste management stakeholders are public and private organisations that provide medical waste disposal and management services. From a sustainability perspective, their feedback is crucial, yet it is often overlooked.

1.2
Healthcare and sustainability: a new combination

In 1996, the U.S. Environmental Protection Agency identified medical waste incineration as the main source of dioxin, one of the most potent carcinogenic gases in the world. For the first time, **health organisations realised that the protection of the environment is directly linked to patient safety** and they chose the Hippocratic principle 'primum non nocere' (first, do no harm) to name the first major international organisation dedicated to promoting sustainable medical solutions, Health Care Without Harm.
Around the same time, a more holistic approach to patient care was gaining traction in the health field. New visions highlighted the interdependence between health and socio-environmental factors. Relevant studies on health futurism investigated the future of human health, opening up the field to environmental sustainability, starting from the analysis of the strong relations existing between the two concepts. The health futurists Hancock and Garrett (1995) observed that "although technological and organisational developments in medical care will have some impact, future health status will be determined largely by the environmental, social, and economic conditions under which people live" (p. 937). Despite the complexity of futuristic scenarios, **the medical sector's responsibility towards environmental sustainability is translated into practice with initiatives addressing very specific issues.** These include substitution of chemical and pharmaceutical products with a high environmental impact, energy efficiency measures in healthcare facilities and, above all, awareness programmes on the environmental impact of hospital routines. While the results have been undoubtedly positive, this fragmented vision of the healthcare system cannot tackle an extraordinarily complex and systemic problem.

In the 2000s, the economic crisis exacerbated the healthcare sector's environmental, social and economic sustainability challenges, which have always been a heavy burden on the public budgets of Western societies. To address this issue, new healthcare associations and hospital organisations emerged, and medical research also began to take an interest in the sustainability debate. Important medical journals published reflections from healthcare professionals who questioned the socio-environmental impact of their medical specialities, as the contribution of Sherman and Ryan's (2010) highlights: "Only through understanding the connectivity and contribution of modern health care practice to ecological issues can physicians work towards aligning commitment to individual care with public and planetary health" (p.139). Although the need to 'establish connections' between medical practice and environmental sustainability is widely recognised, the current approach is still limited by the fragmentation of topics and the lack of a systemic approach in the methods used by medical research to address sustainable healthcare, tackling the topic in a specialised and punctual manner.

The Hippocratic principle had the merit of pushing medical research to question its role towards society and the planet, expanding the concept of health to a holistic view of well-being. However, the complexity of this topic requires a step forward to find convergence points between different disciplines and sectors. This would enable public and private health stakeholders to develop new models that can be implemented at the system level.

1.2.1 Some facts: the socio-environmental impact of the health sector

The health sector is a major contributor to the climate crisis, which is considered the greatest health threat of the 21st century (Watts et al., 2021). The global health sector alone is estimated to produce 4.4% of global greenhouse gas emissions, equivalent to the climate impact of 514 coal-fired power plants (HCWH, 2019). The United States, China and the European Union countries are the largest emitters, causing 56% of the global health climate footprint.
Overall, each country's healthcare sector, directly and indirectly, releases greenhouse gases when providing healthcare and purchasing products, services and technologies from high-impact supply chains. Recent studies identify three main causes of healthcare sector emissions (Figure 1.2):

1. **17% of the sector's global footprint is due to emissions directly from healthcare facilities** and the vehicles owned by those facilities;
2. **12% is due to indirect emissions from energy sources** for electricity and steam production, and for cooling and heating of health care facilities;
3. **71% of emissions come mainly from the supply chain of healthcare systems,** through the production, transport and disposal of goods and services (such as pharmaceuticals and other chemicals), food, medical devices, hospital equipment and instruments.

Therefore, the consumption of energy resources from fossil fuels and the supply of products and services are the most impactful factors for the sector's carbon footprint.
n environmental policies and, above all, in new sustainability strategies for the health sector, the climate impact is the main measure of environmental issues. Although it is an effective criterion for prioritising actions, there are different types of environmental impacts affecting the sector (NCSH, 2019), some with an extremely high carbon footprint, others less critical in this respect but equally important:

1. **Use of chemicals.** Chemicals that interfere with natural systems and cycles pose major environmental and health risks in today's world. Huge quantities of chemicals are used in manufacturing products and devices as well as in healthcare practices, whether sanitisation or medical treatment.

2. **Waste generation.** Waste represents a high economic and environmental cost for healthcare facilities, particularly in relation to the disposal of hazardous or infectious waste. The problem is exacerbated by the use of disposable products and devices, which are particularly prevalent in the health sector in response to infection control standards and regulatory complexity.
3. **Water resources.** Water poses a twofold problem in the health sector: on the one hand, some healthcare treatments and disinfection processes require huge amounts of water; on the other hand, the emission of pollutants through wastewater is a massive environmental and health problem, particularly in the presence of pharmaceutical substances in water.
4. **Energy resources**. Healthcare facilities consume enormous amounts of energy, even more so if we consider the energy impact of the supply chain as a whole. Overall, energy distribution accounts for 40% of the sector's greenhouse gas emissions.

These macro-problems are cross-cutting for the stakeholders involved in the health sector, as they affect health facilities as well as manufacturers and industries involved in the supply chain.

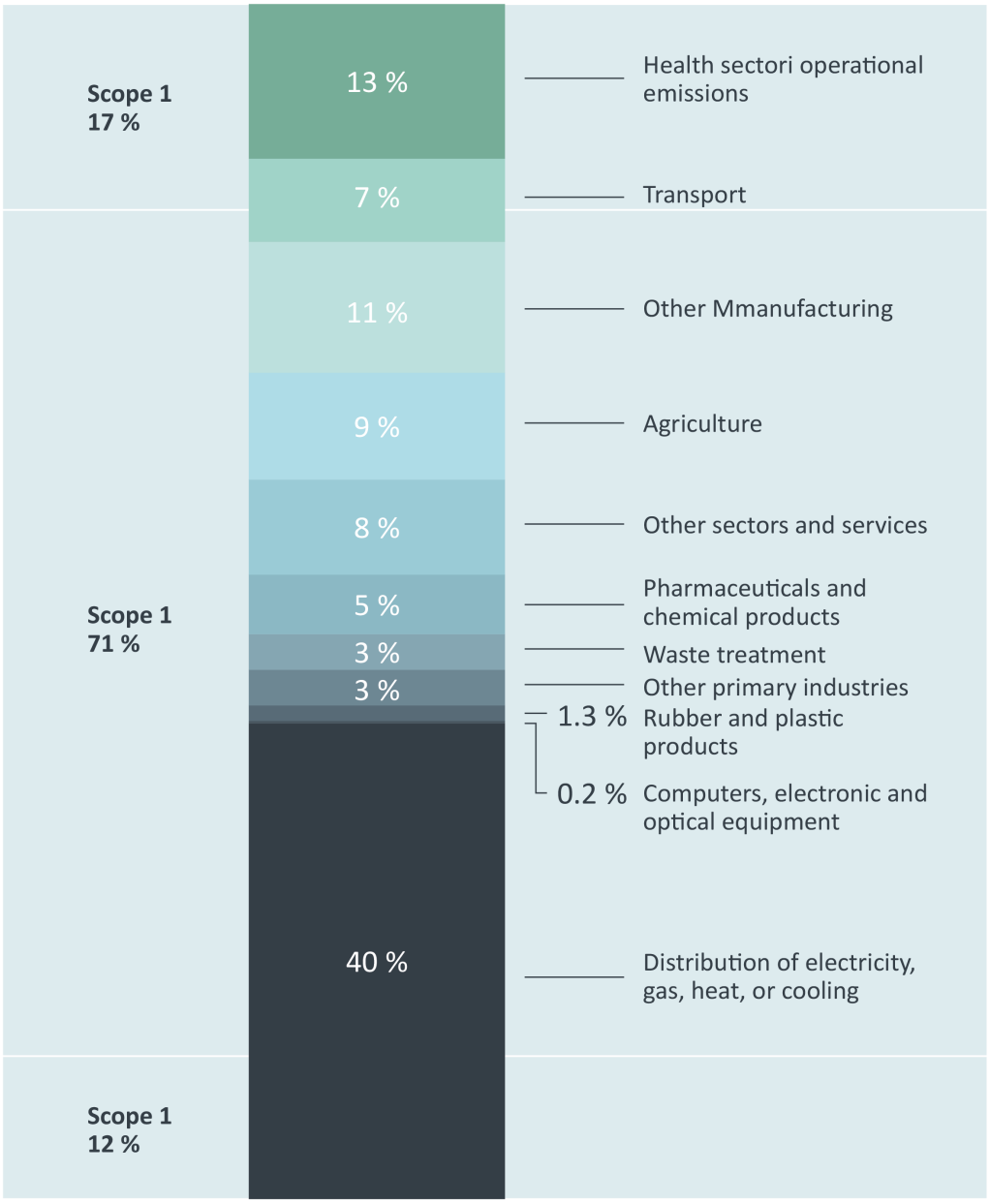

Figure 1.2: *The main environmental impacts of the health sector in terms of carbon emissions (adapted from HCWH, 2019)*

1.2.2 Sustainable healthcare in the European framework

At a European level, healthcare systems have been striving to prevent that the economic pressures arising from the economic crisis (Thomson et al., 2015) and the global pandemic (Atella and Kopinska, 2022) do undermine universal coverage and equitable access to healthcare. Therefore, **the European focus on sustainable healthcare is based on an economic paradigm, starting from a new concept of health system resilience that aims to respond to current challenges and ensure high-quality care also in the future** (European Steering Group on Sustainable Healthcare, 2015). The link between economic and social sustainability is centred on the common goal of providing more efficient and higher quality health services. However, the shift towards a vision that also includes environmental issues is still in progress. Environmental sustainability strategies aim to optimise energy, water and waste and hence reduce their associated costs with a direct financial return on investment. Other environmental initiatives, such as the procurement of non-toxic chemicals, medical devices with fewer chemicals, or healthy food, provide positive patient health outcomes (Sutter, 2012). Despite growing awareness of the link between the three sustainability dimensions in healthcare, the challenge for most European healthcare organisations is how to manage the wide-ranging aspects of sustainable healthcare and integrate them into healthcare operations, given the complexity of actions and stakeholders involved in delivering healthcare services (Boone, 2012).

European attention to the environmental sustainability of public healthcare is mainly focusing on environmental standards for healthcare organisations and the implementation of green public procurement strategies (Chiarini and Vagnoni, 2016). These strategies seek to combine different levels of responsibility of health stakeholders. On the one hand, healthcare providers are directly responsible for the huge resource consumption and waste impacts generated by healthcare processes; on the other hand, the healthcare industry is responsible for some major impacts, such as the presence of chemicals in the environment. The collective attention to sustainability, although discontinuous, is promoting a shared responsibility approach to act upstream and downstream of the healthcare system. Nevertheless, there are still significant differences in the attention given to this issue by different Member States. The Nordic countries are at the forefront of sustainability strategies for healthcare systems and have a strong track record in this area, while other countries are now taking the first steps towards establishing sustainable development plans that explicitly include the health sector. The European Union (EU), based on the principle of subsidiarity, can certainly play a crucial role in promoting more effective

and comprehensive actions in this direction, as has been done for other Community priorities of major socio-economic interest (Guthmuller, Paruolo and Verzillo, 2021).
However, alongside the role of national and European policies, it is important to recognise the drivers that guide the sustainability choices of different actors. Policies can influence or strengthen these drivers, but they mainly rely on socio-economic factors that motivate individual actors, as explored in the next section.

1.2.3 Sustainability drivers in healthcare

Previous studies based on multi-stakeholder foresight processes (Pereno and Eriksson, 2020) have highlighted a change of perspective on the roles of the different stakeholders, also resulting from more direct and continuous collaboration among them (Figure 1.3).
Undoubtedly, **a patient-centred approach to care is being consolidated and patient empowerment is shaping the organisation of the system. The transition from a supply-driven to a demand-driven approach increases the resilience of long-term care systems,** by prompting new health delivery models based on self-care. This also shifts health services from a hospital-centred to a **distributed healthcare approach,** as evidenced by the spread of **new models of home, community and neighbourhood care** (Johansen and van den Bosch, 2017). Although dependent on different socio-economic contexts, patient-centred home care models are reshaping primary care to provide high-quality care tailored to individuals' needs (Jackson et al., 2013), shifting the focus to enhanced interaction between users and health services in the home (Rajkomar, Mayer and Blandford, 2015). In addition to demonstrated improvements in quality of care, distributed healthcare also shows significant cost savings in hospitalisations and improved preventive care (HHS, 2018).

In the face of the patient-centred transition, healthcare providers are evolving in two directions. On the one hand, distributed care requires a greater capillarity of health services through **local units and professionals supporting community and home care.** On the other hand, large health centres are improving their expertise in the management of acute and non-chronic diseases. This requires **defragmentation strategies** to centralise skills and provide high-quality, specialised care for acute conditions. In many countries, this means merging individual hospitals to increase cost-efficiency and deliver high-quality care to a larger number of people (Deloitte, 2016). New technologies are supporting this phenomenon by digitally connecting hospitals, staff, and patients and facilitating **mobile and telehealth services.**

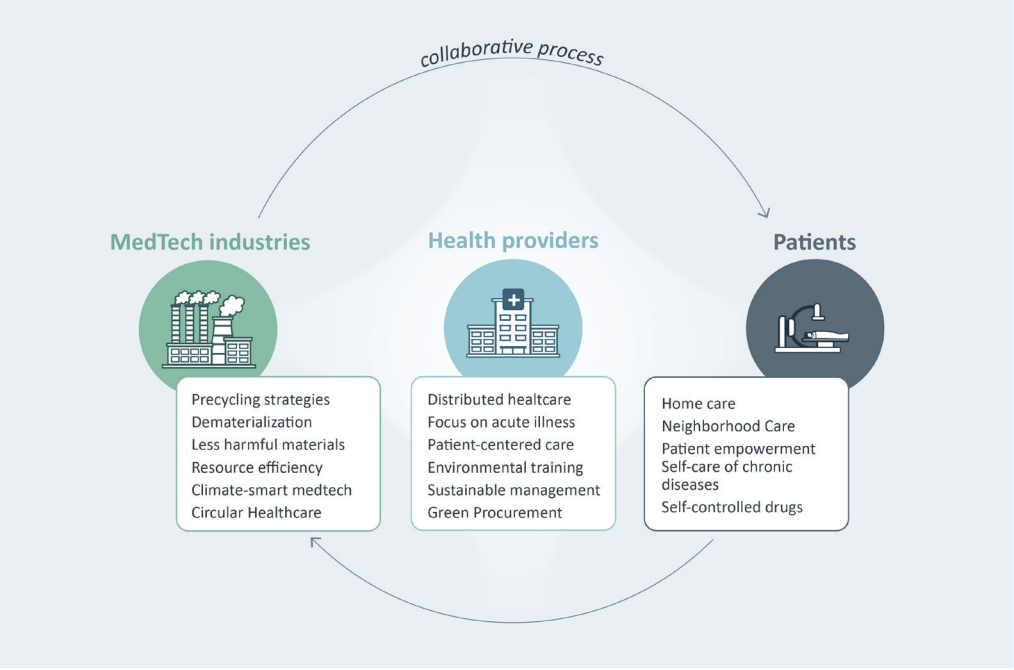

Figure 1.3: *Sustainability drivers and collaborative processes and tools within the healthcare sector (adapted from Pereno and Eriksson, 2020).*

Healthcare providers are also addressing environmental sustainability, implementing strategies and actions for staff training, facility management and dialogue with suppliers. A growing number of **training programmes are dedicated to environmentally sustainable behaviours** (Richardson et al., 2014), particularly for the staff involved in energy and waste management, such as nurses (Ryan-Fogarty, O'Regan, and Moles, 2016). Educational actions are crucial for tackling specific health-related environmental problems and implementing long-term environmental strategies. Management strategies are currently focused on specific issues such as energy efficiency or waste management: in the short term, a systemic approach is needed to align cross-cutting sustainability goals and investments. Among these, procurement strategies are relevant to both innovation and sustainability: **Green Public Procurement** is an established strategy that seeks

to bring together supply and demand in the field of sustainable products and services (Wilson and Garcia, 2011). Other recent instruments include innovation procurement, which aims to develop a (sustainable) product or service not available on the market to meet a real need in the health system, and **value-added procurement,** which shifts the focus from short-term cost savings to a systemic assessment of long-term performance within the health system (EURIPHI, 2020).

In this emerging scenario, the healthcare industry needs to adapt to new sustainability requirements and standards. This demands implementing design strategies to improve the sustainability of products and services. Among these, **'pre-cycling' strategies can help to rethink the current product system** (Greyson, 2007) to reduce upstream waste production and, where possible, the use of disposable products, which have a high environmental and economic cost. The integration of biomedical, digital and clean technologies could support **product dematerialisation** to reduce the impact of physical goods and better meet the demand for distributed healthcare services (Weller, Boyd, and Cumin, 2014). **Data collection and monitoring** will also make it possible to assess the long-term impacts of substances and materials used in healthcare. Moreover, the attention to resource use involves every stage of the supply chain, through the introduction of shared protocols and greater communication between industries, suppliers and distributors to optimise processes and transport. A holistic approach to life-cycle design also allows for a significant reduction in the healthcare industry's carbon footprint, adopting a **climate smart healthcare approach** (Dhillon and Kaur, 2015; Charlesworth and Jamieson, 2019).

Although each stakeholder has its own drivers, their collaboration is paramount in promoting sustainable healthcare scenarios in the short, medium and long term. The problem of 'silos' in healthcare has often led to communication and collaboration gaps within the system (Hajek, 2013). This is exacerbated when new stakeholders, e.g., cleantech companies, are involved. Therefore, collaborative methods and processes are at the heart of the desirable models for sustainable healthcare, enabling shared planning and collaborative dialogue between stakeholders. The integration of systems and design thinking techniques can improve strategic decision-making processes, going beyond short-term products and services (Bühring and Liedtka, 2018) and enabling greater collaboration in the design phase of products and services to meet overarching sustainability and usability requirements.

1.3
Building professional competences in sustainable healthcare

The rapid growth of interest in sustainable healthcare, accelerated by the recent pandemic, is being driven by public and private stakeholders in the sector. Yet, acknowledging its importance and understanding how to seize the opportunities it offers are two separate matters. Awareness of sustainability as a promising issue for the health sector is gradually spreading, albeit with wide geographical variations. As seen above, many networks of healthcare providers are finally getting attention for the work they have been doing for years. On the other hand, the industrial sector is playing catch-up with the new policies and, while understanding their importance, is struggling to incorporate a sustainable approach into its design and management activities.

Indeed, while healthcare providers - hospitals, private facilities, and healthcare professionals – are called to better identify their sustainability needs and assess their impacts over different time horizons, healthcare industry needs to understand how to meet new needs over time. The importance of professional training in sustainable healthcare is evident in both cases.

Hospital and professional associations have pioneered and consolidated training on medical routines, from resource consumption to waste management, also driven by a patient-centred vision leading to planet-centred care. As discussed above, a systemic approach is often lacking and issues risk being addressed in a piecemeal manner. Still, it is undeniable that much effort has been made to offer valuable educational tools.

On the industry side, the educational landscape for sustainability in healthcare is hugely deficient. There are training courses on digital or manufacturing technologies that can have important applications and positive environmental spin-offs (e.g., additive manufacturing or augmented reality), but there is a lack of training programmes that can provide design skills to tackle the product and service innovation required by sustainable healthcare.

1.3.1 Job and skills transition in a sustainable healthcare scenario

The idea of sustainable transition in the industry suggests the need for new green professions and sustainability specialists. However, this is only half the story. New vocational skills are needed to address new sustainability trends, but it is estimated that most re-training takes place on the job, while education or additional qualifications can be combined but are less prominent (Bowen, Kuralbayeva and Tipoe, 2018).

From this perspective, it is important to distinguish different subcategories of jobs (Dierdorff et al., 2011), which differ in terms of how sustainability affects the tasks, skills, and knowledge required (Figure 1.4):

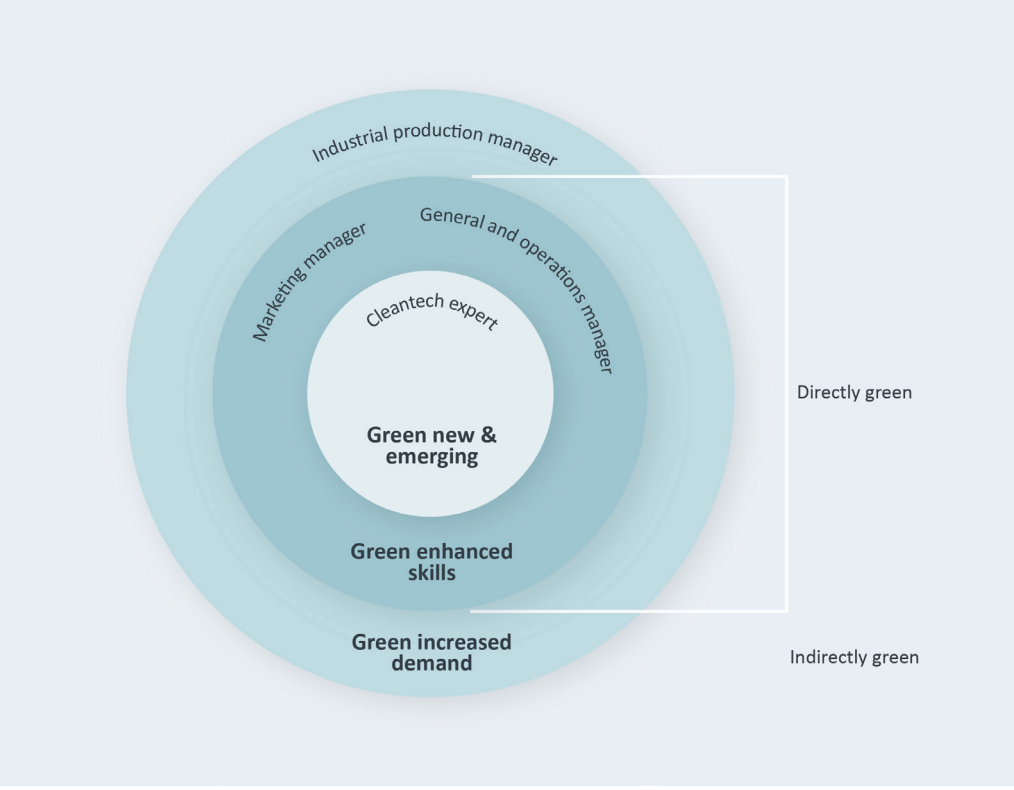

Figure 1.4: *Green jobs categories, adapted from Dierdorff et al. (2015).*

- *Green Increased Demand* are existing jobs that are expected to be in high demand due to a sustainability transition, but do not require significant changes in tasks, skills, or knowledge. They indirectly support sustainable economic activities but do not involve any green tasks.
- *Green Enhanced Skills* are existing jobs that require significant changes in tasks, skills, and knowledge to meet the demand for sustainability.
- *Green New and Emerging* are unique jobs created to meet the new needs and worker requirements related to sustainability.

Green jobs cut across many sectors and green new and emerging jobs are particularly relevant in some of these. However, in most cases, the **sustainable development of an industry is mainly concerned with green enhanced skills jobs, which are based on sustainability training and involve on-the-job training processes and continuous education of employees in line with a company's sustainability goals.** Many studies have shown that this type of training is a skill-enhancing practice, which increases employees' sustainability awareness, knowledge, and skills and underpins solutions to reduce the company's environmental impact (Pinzone et al., 2019). Personal environmental motivation is a powerful driver for staff, especially when supported by the employer, but unlike other sectors, healthcare is particularly challenging in this regard. However, studies in the sector show that investing in professional training for sustainability means improving employee satisfaction and performance and building internal competencies to seize market opportunities.
It is therefore worth understanding which sustainability issues may impact the healthcare sector in terms of tasks, skills, and knowledge.

1.3.2 Sustainability training goals and contents

Training staff in sustainability means providing them with continuous learning tools to develop new knowledge and skills to practically improve sustainability in their daily tasks. Regardless of the sector, effective sustainability training should address some overarching learning objectives (Pinzone et al., 2019):

- **raise managers' and employees' awareness** of how their work activities and decisions affect the environment;
- provide employees with the **skills to identify environmental issues in their daily work;**
- provide employees with the **skills to understand and manage the complexity of environmental issues;**
- enable employees to fulfil their environmental responsibilities and **achieve the organisation's environmental objectives.**

The training contents can vary greatly: from learning specific techniques (e.g., carbon footprinting for healthcare) to sustainability strategies in specific areas (e.g., waste prevention and management) or in sector-specific areas (e.g., kidney care). But first of all, the healthcare industry needs to start by raising awareness among its employees and motivating them, introducing a topic that is radically new to many of them.

For this reason, the following chapters will first provide a general introduction to sustainable healthcare with a specific focus on MedTech. After presenting the basic concepts and the main environmental and social issues, we will look at two levels: the product and the system. At the product level, new concepts such as Circular Product Design open up important reflections on strategies to reduce products and processes and adopt a life-cycle approach in MedTech, which can bring radical economic and environmental benefits. At the system level, understanding the implications of a systemic design approach and environmental management strategies is crucial to synergistically tackle the challenges that sustainable healthcare poses for the design and management of MedTech solutions.

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2

Sustainable and circular healthcare

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Amina Pereno wrote par. 2.2 and 2,3, Daniel Eriksson wrote par. 2.1 and 2.4.

2.1
Sustainability and sustainable healthcare

Sustainability is often defined in terms of its three dimensions, namely ecological, social and economic. To meet the challenges of today and tomorrow and to contribute to sustainable development, all three dimensions must be taken into account.
The **social dimension** encompasses all such factors and elements that relate to people and society. Health, well-being and healthcare have an obvious place in this dimension – as they are by their nature a fundamental societal service, providing people with access to vital care services. The **ecological dimension** refers to all human societies in relation to the physical environment, the planet and all its ecophysical systems and parts – such as the climate. Global healthcare accounts for about 4.4% of global emissions (HCWH, 2019), making it one of the priority sectors for a sustainable transition. The **economic dimension** is more vaguely and unanimously defined, but refers to the economic system in which the planet and society reside. Some point to the economic dimension of sustainability as a tool and even a prerequisite for sustainable development as such, while others place greater emphasis on the economic dimension as a way of facilitating, for example, circularity and a more sustainable management and distribution of resources.
Governance, or 'good governance', is sometimes referred to as the third pillar of sustainability, focussing on the importance of governance in promoting action and implementing policies and plans. Governance is relevant on both macro level and meso level, as both are populated by policy- and decision-makers who influence priorities and behaviours. Social responsibility is used to describe the contribution of organisations and companies to sustainable development.

2.1.1 Sustainability in healthcare

When considering sustainability in the broader healthcare sector and in the different health systems, the context is a necessary starting point. Healthcare's vital role and function as a service provider to citizens most often entails that national, regional and local policies impact its nature and character. In essence, **sustainability in healthcare is therefore related and correlated to the sustainable development of countries and their well-being as a whole.**

From a systemic perspective, sustainability in healthcare is not limited to its core services but encompasses a wide range of processes and activities that take place inside and outside of its operational facilities (Figure 2.1). In addition, the diversity and number of actors should be extended to a wide range of stakeholders, from patients, doctors and administrators, those responsible for supplying transport, research and knowledge, products and components, and solutions for waste, water, electricity, and so on.

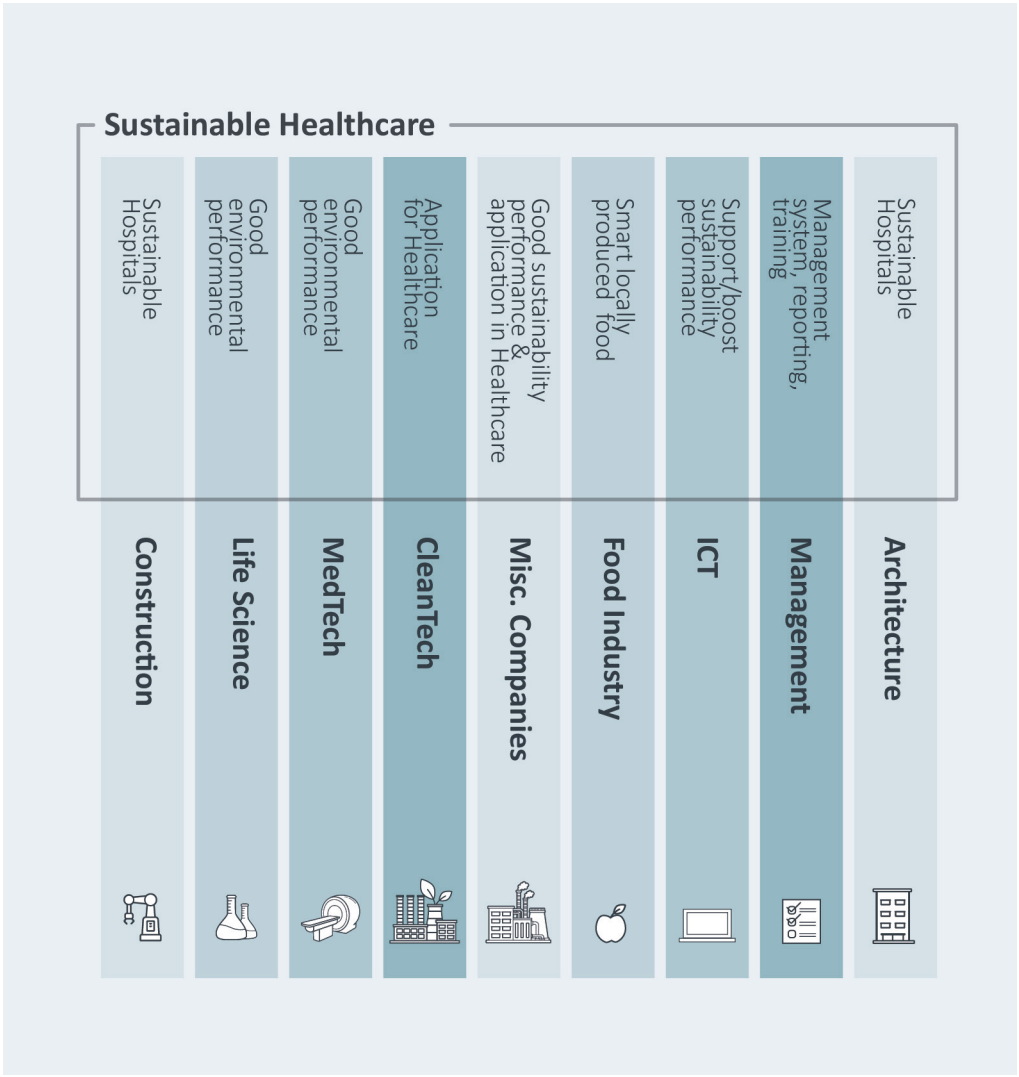

Figure 2.1: *Sustainable Healthcare as an overarching strategy covering the different 'silos' that make up the healthcare sector (source: NCSH, 2020).*

Given the breadth of the health system, its interdependence on other systems, and the abundance of different actors and processes related to its nature and functioning, a holistic perspective on how to address sustainability challenges is needed. **The transition towards a more sustainable sector requires each node and actor in the system to identify and target the social and environmental aspects that are most relevant and impactful.** Working strategically with sustainability means both being aware of the place of organisations in the healthcare value chain, but also that strategies and activities to address the most relevant aspects need to be specific and supported by policy and governance at both the macro and meso levels.

The relationship between health and the environment, and the fact that health and healthcare organisations represent a large portion of a country's environmental impact shows that healthcare, and its providers have a major responsibility to address these issues. However, there are specific challenges in healthcare that are not usually found in other types of industries and operations. Sustainable healthcare encompasses sustainability issues such as pharmaceuticals, radiation, radioactive waste, infectious and sharps waste, security-classified waste, sterilisation, nitrous oxide/ anaesthesia, isocyanates, single-use materials and 24-hour operations.

Another factor that distinguishes sustainable healthcare from other sustainability work in other operational areas is the **focus on patients and patient safety as a centre of attention.** This can mean , for example, using treatment methods – or pharmaceuticals –that may have a substantial impact on the environment, but are crucial for the treatment and healthy recovery of patients. Impacts on the working environment of staff and on the external environment are sometimes given a lower priority than in other industries – and as such may be addressed through different types of protective measures rather than prohibition.

2.1.2 The UN Sustainable Development Goals (SDGs)

Sustainability is also often described in terms of the global goals for sustainable development, adopted by the United Nations in 2015. The 17 Sustainable Development Goals (SDGs) are part of the 2030 Agenda (UN General Assembly, 2015), and its overarching purpose is to eradicate poverty, reduce inequality and injustice in the world, and solve the climate crisis. These **SDGs can help an organisation connect its local operations to a global context** and clarify how the company can contribute to the global agenda.

Sustainable healthcare is represented in SDG 3 - Health and Well-being, which focuses on good health as a fundamental prerequisite for people's ability to reach their full potential and contribute to social development. Individual health should be seen as influenced by many economic, environmental and social factors. SDG 3 addresses all of these dimensions and targets people of all ages.
The UN SDGs are a widely accepted universal framework for formulating goals, sub-goals and measuring progress using the indicators included. As such, the SDGs provide a common language and priorities to inspire and communicate goals and ambitions for sustainability work.

2.1.3 Sustainable Development Goals and circular economy

In parallel with the UN's definition of the SDGs, the European Commission (2015) launched its first Circular Economy Package, identifying the circular economy model as an approach to achieving local, national, and global sustainability (Schroeder, Anggraeni, & Weber, 2019). The European Commission (2018) itself acknowledges that "the circular economy (SDG 6, 8, 9, 11, 12, 13, 14, 15) offers a transformative agenda with significant new jobs and growth potential and stimulating sustainable consumption and production patterns. [...] The transition to the circular economy offers a chance for Europe to modernise its economy, making it more future proof, green and competitive" (p. 8). From the outset, Europe has read the SDGs and the circular economy synergistically, investing in the circular transition to achieve most of the 17 SDGs (Rodríguez-Antón et al., 2022). Indeed, the circular economy introduces new consumption and production patterns that decouple human well-being from environmental degradation through circularity (Sachs et al., 2019).
Circularity is often associated with promoting the reuse and recycling of materials, but these are only some of the strategies underlying new production patterns. Understanding the phenomenon that underpins all SDG transformations is essential to avoid oversimplification, while also harnessing the potential that the circular economy can offer businesses in the short to medium term. Therefore, the following sections will elaborate on the definition of the circular economy and explore its implications for the healthcare sector and the MedTech industry in particular.

2.2
Basics of circular economy

In recent years, the term 'circular economy' has become increasingly common, seemingly supplanting the concept of sustainability. In fact, the circular economy model is deeply embedded in a sustainable development approach to our societies.
Indeed, the growing focus on sustainability has made it possible to move from analysing the problems (greenhouse effect, waste production, environmental impacts, etc.) to tackling the causes. Addressing environmental issues from a systemic perspective inevitably involves working on the current 'linear' economic model, which has contributed to generating the social, environmental and economic impacts and inequalities we are experiencing today. Thinking about improving the sustainability of a business is self-limiting if we do not take action and look at the big picture. Therefore, the last decade has seen the consolidation of a new macroeconomic model: the circular economy. There are many definitions, but the one provided by Korhonen et al. (2018) brought a complete perspective on this topic in relation to sustainable development and sustainability science:

> *"Circular economy is an economy constructed from societal production-consumption systems that maximize the service produced from the linear nature-society-nature material and energy throughput flow. This is done by using cyclical materials flows, renewable energy sources, and cascading type energy flows. Successful Circular Economy contributes to all the three dimensions of sustainable development. Circular Economy limits the throughput flow to a level that nature tolerates and utilizes ecosystem cycles in economic cycles by respecting their natural reproduction rates".*

In this definition, we find all the key aspects of a circular model: production systems are still at the core of our economies, but the way resources are managed is changing radically. as the very concept of waste no longer exists. Resources are being kept in the production loops for different uses and purposes to increase their overall value. This balances the environmental, social, and economic dimensions that enable our development while respecting the natural ecosystems in which we live. The following sections will investigate the implications of circular economy models for the healthcare and MedTech sectors, starting with the current and exploring present and future opportunities.

2.2.1 The untenability of current linear models

Current economic models are based on the 'take-make-waste' paradigm that builds on a linear approach to reality. We have always thought of industrial systems as circumscribed, determined, stable, and objectifiable. The truth is that we cannot set the boundaries of an industrial system, if not artificially (Rith & Dubberly, 2007). We must acknowledge that our world comprises open, changeable, multifaceted and undefined systems. An industrial system involves a vast network of stakeholders and many territorial systems linked to each other. We supply resources from local or, more often, global contexts that differ from the manufacturing sites, which in turn differ from the systems in which the products or services are distributed. That means every supply chain affects an infinite number of social stakeholders in a more or less direct way.

Studies and reports over the past 60 years have demonstrated that this linear model cannot last (Geissdoerfer et al., 2017). The point is that **it is a linear model based on the infinite use of resources, which collides with an indeterminate world in which resources are finite. The question then is not whether to change our economic and business models but how.**

If the linear macro-model of our national economies collapses, linear micro-models will face the same fate. Therefore, approaching the new circular and sustainable models is crucial for any company: playing ahead means being able to be successful in the future.

2.2.2 Principles of 'circularity'

At a macro level, the circular economy was born to address what can be called "wicked problems" (Rittel & Webber, 1973). A wicked problem is an open and complex problem that cannot be clearly, objectively and unambiguously defined and therefore, cannot be investigated and solved using traditional problem-solving methods. Climate change, global crisis, and biodiversity loss are wicked problems because of their complexity, which cannot be faced in a single, standard way.

The Ellen McArthur Foundation was one of the first institutions to promote and implement circular models (Figure 2.2). Based on its contributions, we can state that **the circular economy model looks beyond the current economic and industrial model. It is restorative and regenerative by design.** Based on system-wide innovation, it aims to redefine products and services to design out waste while minimising negative impacts. Underpinned by a transition to renewable energy sources, the circular model builds economic, natural and social capital. It can be summarised in a few key points (Bompan & Brambilla, 2018):

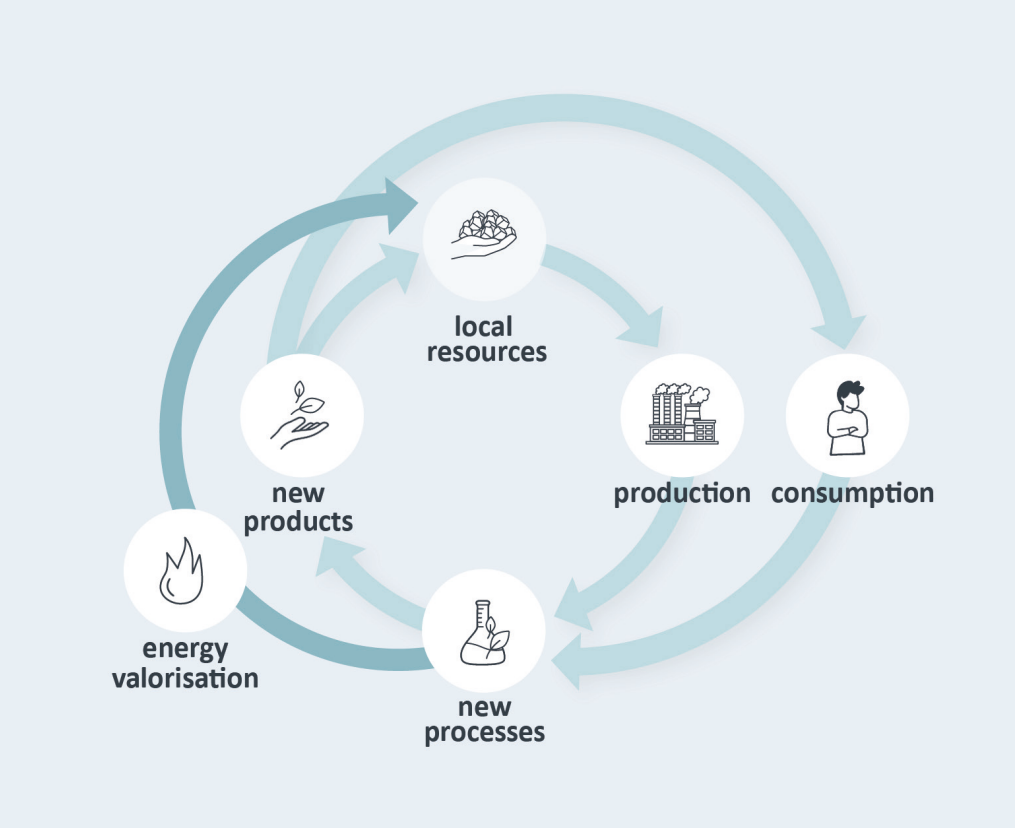

Figure 2.2: Graphic visualisation of the life cycle of goods in a circular model

Regenerative by design. In a circular economy, we design the entire life cycle of a product/service. This includes but goes beyond the current concepts of reuse and recycling, such as maintenance, repair and remanufacturing, become priorities. In this perspective, the design of products and services throughout their life cycle is crucial to overcome today's limits of recoverability, often imposed by design based on the linear paradigm.

New products and services. Changing the production system also calls for innovation in products and services. Conceiving a product in a circular dimension requires a change in business models and what is offered to users.

Abandoning the concept of waste. A cultural, legislative and ultimately productive change is needed to start thinking of waste as a new resource for other internal processes or for other companies and sectors. Abandoning the idea of 'waste-to-be-disposed' is a fundamental starting point.

If we look at the strategies being implemented by the European Commission (2015; 2018), we find these key points translated into five principles that guide the European transition to a circular economy. These are explained in detail in the Ellen MacArthur Foundation report "Towards a Circular Economy: Business Rationale for an Accelerated Transition" (2015):

The first principle is that **waste is designed out.** In a circular model, waste does not exist because biological and technical components or materials are designed to fit into circular material cycles. This means, for example, that polymers, alloys, and other man-made materials are designed to be recovered, renewed and upgraded so that they can be used for as long as possible (Bilitewski, 2012), thereby minimising resource consumption.

The second principle is that **diversity builds strenght.** In living systems, biodiversity is essential to survive environmental change. Similarly, in industrial models, diverse multi-scale systems are more resilient to external shocks. Larger companies bring scale and efficiency, while the smaller ones provide alternative models in times of crisis (Goerner et al., 2009).

The third principle is that **renewable energy sources power the economy.** This is because they reduce resource dependence and increase the resilience of our technological systems (e.g., to oil shocks). We should also consider the embodied energy of a product's life cycle to minimise the need for fossil fuel inputs and maximise the energy value of by-products.

The fourth principle is to **think in systems.** People and businesses are part of complex systems in which all parts are interconnected. The ability to understand how different industrial processes and systems affect each other is fundamental. Systems thinking can increase flexibility and adaptability to changing conditions.

The final principle is that **prices reflects real costs.** European policymakers are implementing specific measures to promote greater transparency on externalities (Webster, 2015), as this can be an obstacle to the transition to a circular economy based on fair competitiveness.

2.2.3 A sustainability transition towards a circular economy

If the theory is increasingly clear, the practice is much more complex and sometimes murky. How will our industries get to a circular economy? According to futurists and transition experts, **all sustainability transitions follow a standard path.** One of the most established theories is the multi-level perspective (MLP) model by Frank Geels (2005; 2008). In simple terms, it stresses the need to start from an experimental niche to test a new model or technology and to break the standard - called regime - to establish a new, better and sustainable model.
This is even clearer if we look at the 'X-curve framework' by the Dutch Research Institute For Transitions (Loorbach & Rotmans, 2010; Hebinck et al., 2022), summarised in Figure 2.3. Experimentation is the first step for a bottom-up sustainability transition; acceleration helps to cope with an emergency situation. The success of sustainability experimentation leads to its institutionalisation and to a stability phase in which it becomes a widespread practice. This also marks the phase-out of the existing model.

Beyond the theoretical implications, which would require extensive study and discussion, it is crucial to emphasise that **sustainability transitions in practice start from the bottom up and from the willingness of companies to experiment on niche processes that can be scaled up.** Top-down strategies show us that the interest in pursuing scalability and transfer between different sectors and regions is a priority. Being among the 'experimenters' and understanding the transition before it becomes an institutionalised reality will give front-runner industries a huge competitive advantage.

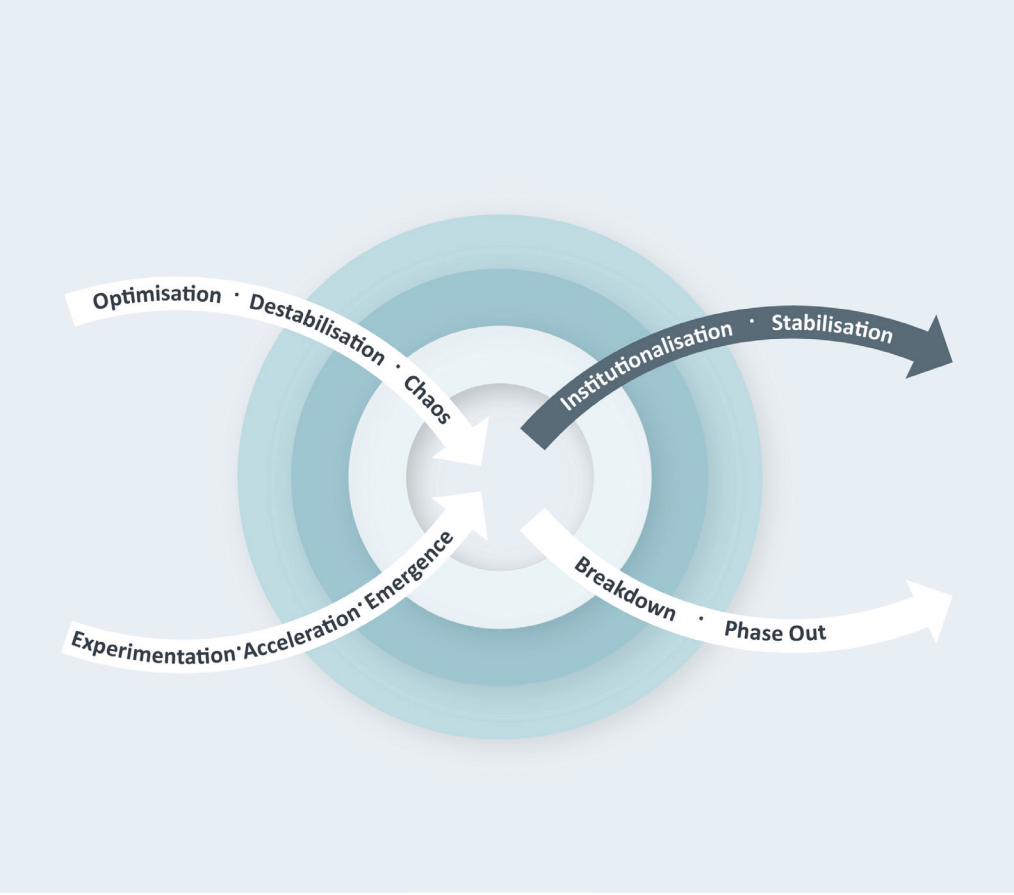

Figure 2.3: *The 'X-curve framework' for sustainability transition (elaborated from Hebinck et al., 2022)*

2.3
Circular Healthcare and circular MedTech

To date, even the most advanced organisations in the field of sustainable healthcare have often taken a piecemeal approach to the problem, implementing strategies and actions on a few specific issues, from waste collection to home care.
The growing focus on the circular economy reinforces the urgency of building a more holistic and collective vision of sustainability in the healthcare sector, defining an overall framework allowing with clear and achievable goals to be set in the short, medium and long term.
This requires a systemic approach that considers the entire life cycle of health products, services and systems, from management and design to production and transport, from use to disposal and reconfiguration.

2.3.1 Barriers to the circular economy in the MedTech sector

Our healthcare systems rely on linear supply chains consisting of single-use, disposable medical devices (MacNeill et al., 2020). This has led to increased healthcare expenditure, waste generation and the associated pollution. It has also made the supply chain vulnerable to disruptions and fluctuations in demand (Sherman et al., 2020). Therefore, the shift of the MedTech industry toward a circular economy can have a twofold positive effect:

1. **Reduce the environmental and social impacts of the sector** by minimising waste production and encouraging new business models that increase product value over time, with positive outcomes for patients and stakeholders.
2. **Increase the resilience of healthcare value chains by making MedTech companies more competitive** and less sensitive to fluctuations in demand and potential shocks on a global scale.

However, there are **many factors that have led to the current "single-use dominant" model and are hindering a circular transformation of the MedTech sector** (MacNeill et al., 2020). These include the perception that single-use devise are safer than reusable devices, even because they provide a relatively easy way to minimise the possibility of human error in reprocessing reusable devices. In addition, current business models incentivise single-use devices to maximise profits through high-volume consumption. In contrast, circular service-based models focus on quality and durability, reducing production volumes in favour of high-value-added solutions. Finally, the lack of clear and consistent guidelines from national and international policymakers leads to confusion around standards for reusable device reprocessing.

2.3.2 A road map for a circular healthcare industry

The diagram in Figure 2.4 summarises the key topics of sustainable healthcare in relation to the life cycle stages of healthcare solutions, whether products or services. At each stage, different stakeholders can be involved by sharing their needs and requirements or by responding to these needs through industrial and management solutions.
Overall, the circular economy trends for the health sector can be summarised in four macro-areas: sustainability goals, health and environmental standards, sustainable product strategies, and sustainable system strategies.

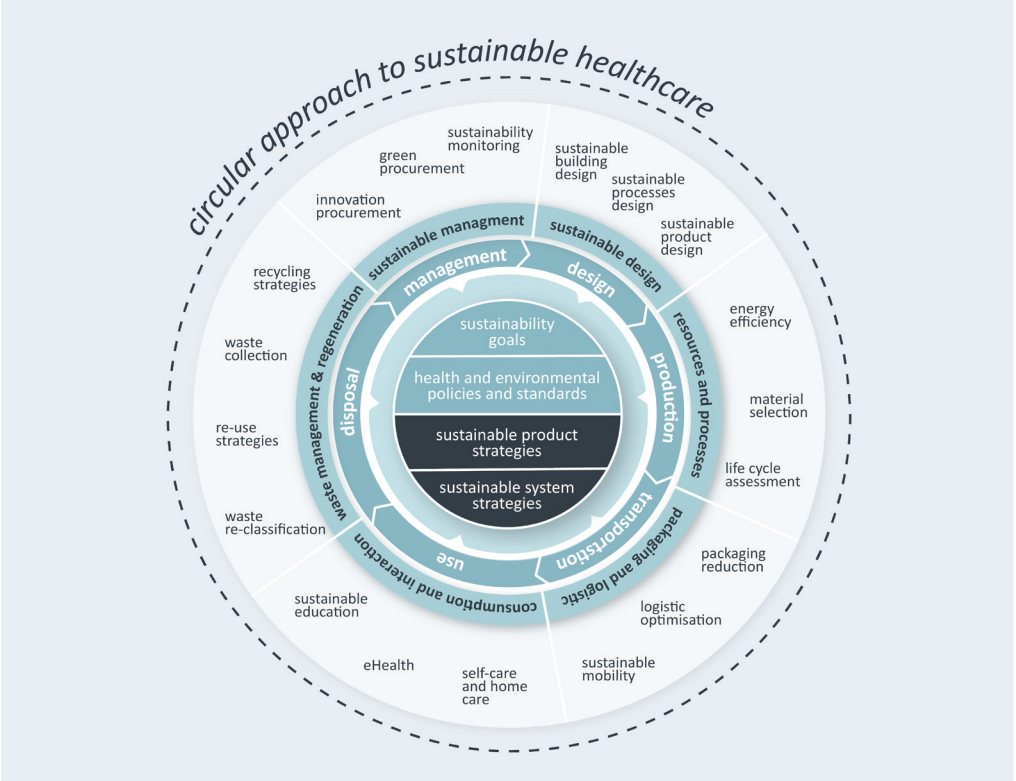

Figure 2.4: *A circular approach to sustainable healthcare (source: Pereno, 2021)*

Sustainability goals

If there is still confusion at the international level about the definition and content of a sustainable healthcare approach, there is an even greater need at the national and regional levels for a basic and shared understanding of the topic. Recent studies show that **sustainability should be integrated with health quality** (MacNeill et al., 2020; Sherman et al., 2020), **towards an idea of 'high-value care',** which, in practice, means working towards greater effectiveness and efficiency of the healthcare system, starting from the interactions between environmental problems and their economic and social impacts. For example, the design of reusable medical devices addresses an environmental problem (the production of waste), an economic problem (the disposal of medical waste), and a social impact (the possibility of investing in the design of the device to encourage its use by the user in a self-care perspective).

To build this awareness, **it is first necessary to invest in training.** For many healthcare professionals and companies, environmental sustainability is still an abstract concept that has nothing to do with their work. Talking about sustainable healthcare and providing training opportunities at all levels is crucial. It is necessary to start from the basics in order to integrate aspects of environmental sustainability into hospital routines as well as into the design of medical devices, proposing a systemic approach to the issue to raise awareness of the close relationship between health, the environment, and the economy.

Based on the characteristics of a local health system, it is necessary to set clear and shared objectives, not only in the short term but, above all, in the medium to long term. This concerns not only regional decision-makers, who are essential in promoting a circular approach to health, but also the other stakeholders who together with hospitals, companies, research institutions and other associations, define sustainability goals in order to create a regional and national agenda that respects the specificities and needs of each individual.

Health and environmental policies and standards

European and Italian legislation comprehensively regulates products, devices and services in the healthcare sector, often requiring certification and considerable effort to update companies and suppliers, as in the case of the new European Regulation on medical devices 2017/745. **In addition to sector-specific regulations, the healthcare industry is often subject to environmental regulations that may affect certain types of products** (NCSH, 2019): the RoHS Directive on the restriction of the use of certain hazardous substances in the construction of electrical and electronic

equipment; the REACH Regulation on the identification and management of risks related to chemicals; the CLP Regulation on the classification, labelling and packaging of chemicals and their mixtures; the POPs Regulation, which prohibits or restricts the production and use of substances that pose particularly serious risks to health and the environment; and the strategies related to extended producer responsibility (EPR) and incentivised by the Circular Economy Package for numerous types of product. In particular, the strategies proposed by the Circular Economy Package 2015 and 2020 have the value of proposing a comprehensive action plan, which, beyond its inherent limitations, aims to lay the foundations for a more systemic view of products and waste, from their design and maintenance to their end-of-life.

This long-term strategic perspective is crucial for sustainable healthcare policy. Again, the socio-environmental dimension is based on an economic perspective, since a sustainable healthcare system must first and foremost keep financial costs under control. Although it is not possible to define a clear strategy on how to ensure the economic sustainability of the system, there is a shared understanding of the need to **promote changes in the behaviour of patients and healthcare providers** (Fischer, 2015). On the one hand, by promoting activities that improve health and prevention, and on the other hand, by incentivising healthcare providers to maximise the value for money of products and services through training and routine optimisation strategies that combine environmental, social and economic benefits.

This requires **long-term planning to replace the piecemeal, incremental decision-making that has often characterised environmental decisions.** A strategic vision enables the promotion of scientific and technological innovation in a complex system such as health, helping to improve health services, develop effective drugs and products, and reduce administrative barriers. Innovation is the key to maintaining long-term competitiveness. However, this requires the search for innovative financing models, such as value-added procurement, which shifts the focus from short-term cost savings to a systemic evaluation that includes performance within the health system and benefits to patients and the environment, prioritising long-term efficiency (Prada, 2016). Or innovation procurement, which allows the development of a product or service that is not available on the market, in response to a concrete need in the health system, through a form of a dialogue between healthcare providers and health suppliers that can take different forms at the national or transnational level (EURIPHI, 2020).

Sustainable product and system strategies

The environmental problems of the health sector are neither punctual nor easy to define, as they have impacts at different levels and involve different actors and sectors. For this reason, it is crucial to approach the circular economy and sustainable healthcare from a systemic perspective, working on corporate policies that provide for gradual but goal-oriented innovations in the short, medium and long term (Pereno and Eriksson, 2020).

In the following chapters, we will explore how procurement models for goods and services are evolving towards greater collaboration between public or private customers and suppliers: this is also leading to **a growing inclusion of environmental and social sustainability parameters in procurement processes.** Meeting these new requirements is a major challenge for all companies, one that needs to be addressed at two levels. At the product level, it is necessary to explore the **opportunities offered by circular product design strategies.** In a nutshell, this means designing durable products that can be easily disassembled, remanufactured and repaired. Modularity, adaptability, and versatility strategies are at the heart of the circular design. At the system level, there are two main macro-strategies that a company can follow. **The first strategy focuses on reuse:** a company can establish new forms of communication and supply management with customers, for example, by setting up collection and management systems for used medical devices to be remanufactured. **The second strategy focuses on new performance-based business models:** several types of circular business models can be implemented, but, in general, service-based models can encourage the production of reusable medical devices while increasing customer loyalty over time.

2.4
Key environmental and social aspects in sustainable healthcare

Sustainability in healthcare is a broad topic with many aspects and actors. A holistic perspective means including social and environmental issues of the entire system, as well as other and larger systems. As part of a larger ecosystem, healthcare needs to acknowledge the many issues that are relevant to contribute to sustainable development, while at the same time focusing on and prioritising those social and environmental issues where the sector's impact is greatest.

2.4.1 A few key environmental topics

The issue of the environment has never been more important or more relevant than it is today. As a healthcare organisation, one has a responsibility to identify its negative impact, and work to minimise it. Some of the key environmental issues are briefly described below.

Resource efficiency

Environmental work and resource efficiency, which leads to cost savings, often go hand in hand. **Significant cost savings can be achieved by reducing the amount of material used in production.** There are also opportunities to make savings through the **amount of materials in a product,** without altering a product's characteristics. Resource efficiency can include reducing the amount of chemicals used in production, or recirculating water and chemicals in the process for a more efficient use. Reducing the energy—or water—consumption of a product in a production process or in the facilities where production takes place can lead to both environmental and economic benefits.

Chemicals

Chemicals that disrupt natural systems and cycles pose a large environmental and health risk in today's world. Large amounts of chemicals are used in the production of various products, and their residues are not always managed in a safe and sustainable way. This contributes to the spread of chemicals harmful to the environment and health that we struggle to monitor or understand the long-term consequences of.

Careful consideration should be given to the types of chemicals to be used. Options that are harmful to the environment and health should always be avoided to the greatest extent possible. Different countries often have environmental legislation that can help guide the selection of chemicals. In Sweden, for example, regional municipalities also draw up chemical substitution plans that indicate which chemicals are banned or should be phased out as far as possible.

Chemicals used in operations should be documented and assessed for risks.

It is also essential that information on the properties and hazard levels of chemicals is provided to the people who use them in practice. Safety equipment may be required for safe use and the environmental risks associated with emissions need to be minimised. An important aspect of the strategic work is to maintain good procurement practices. Responsibility for purchasing and procurement should be in the hands of only a few individuals with the necessary expertise. An environmental and occupational safety assessment should be done before purchasing any new chemical that is introduced.

There are extensive regulations governing the management, use and labelling of chemicals. These include REACH, the CLP Regulations, and the RoHS Directive.

FOCUS:

Forever Chemicals

Per- and polyfluoroalkyl substances (PFAS) are a class of over 9000 persistent hazardous chemicals used in industrial processes and consumer products (Land et al, 2018) that have been produced since the 1940s (Glüge et al., 2020) with very different physical, chemical, and biological properties including polymers and non-polymers; solids, liquids, and gases (Buck et al., 2021).
Their molecular structure contains fluorine-carbon bonds and is both hydrophobic and lipophobic (Land et al, 2018). The strength of the bonds in their molecular structure makes them unbreakable or slow to break down under natural conditions, which is why they are also called 'forever chemicals' (Kwiatkoskwi at al., 2020).

Due to their high persistence, they accumulate in the environment - in water, air, soil and living organisms - increasing the risk of harm. As they can also accumulate in plants via contaminated soil or irrigation water and thus in crops, they cause a bioaccumulation process via the food chain. Furthermore, human and environmental exposure can occur at all stages of the life cycle of these chemicals or products containing them, such as production of the chemicals, manufacture of the products, use, distribution, disposal, etc. Moreover, their accumulation is not strictly limited to the areas surrounding their source. In fact, the high mobility of these compounds means that they can travel very long distances, and their solubility in water and persistence result in their global spread, even to remote regions such as the Arctic (Kwiatkoskwi at al., 2020).

Their use in industrial products and processes is widespread, particularly in the manufacture of medical devices. Their accumulation can reach concentrations that are hazardous to human health and ecosystems. Once ingested, these substances are well absorbed by the body, resulting in their distribution from the organs to the blood to the tissues, with a wide range of effects on the body. (Kwiatkoskwi at al., 2020). Exposure through consumption of contaminated water has effects such as testicular and liver cancer, ulcerative colitis, pregnancy and fertility problems, liver and thyroid disease, and elevated cholesterol levels.
Even low levels of exposure can have adverse health effects, and even prenatal exposure to these substances has been linked to an increased risk of cardiovascular and respiratory disease (Cordner et al., 2021).

To learn more about the commercially relevant PFAS from an industrial point of view, see the table in this article (🔎, Buck et al., 2021) and to learn more about the different categories of use, see the table in this article (🔎, Glüge et al., 2020).

Waste

Waste entails both a cost and an environmental impact. Every business should therefore strive to minimise the amount of waste it produces. That specific portion of waste which is classified as hazardous should be handled with special precaution and should be mixed with other types of waste. Examples of hazardous waste include residual chemicals, electronics and batteries. Healthcare operations often have their own waste plans and rules on how to sort and minimise waste. **The amount of hazardous waste sent off must be documented for the different categories.** In addition, those transporting and receiving the waste must have the appropriate permits to do so. It may be well worth investigating where the waste is generated and whether there are ways of reducing it.

Transport

Transporting products all over the world is a major contributor to climate change. The type of transport used has a major influence on the environmental impact. Rail transport is preferable, especially in countries where a lot of energy is produced from non-fossil fuels. Air transport is the one option with the most negative environmental impact. Fossil-fuelled aircraft should therefore only be used when all other options have been ruled out. In addition, materials and products be chosen that do not require long journeys should be chosen. It is also necessary to consider the requirements that may be placed on transport suppliers in the choice of fuel.

In addition to the transport of products and materials, a company may also review its business travel. Travelling by train is preferred as an alternative to domestic air travel, and most meetings can now be conducted remotely using online/digital solutions. If company cars are provided, it may be relevant to have requirements for the environmental performance of the vehicles. Travel policy and/or business care policy can support the shift towards more sustainable transport.

Water

Water is a necessity for all life, and an important resource for industrial production. In some countries, water shortages have only recently become a concern, with insights into and discussions of how low groundwater water levels is becoming more frequent and what the relationship with climate change is. What can be discharged into urban or municipal sewer systems is often highly regulated. Permits are also required for the release of sewage from manufacturing and industrial processes. Thresholds for emissions of various substances are most often set, for example, in local regulations.

Water consumption and emissions of various pollutants to water are a major issue in countries where many life science companies have their subcontractors. There are major concerns surrounding the production of pharmaceuticals in certain countries, where huge amounts of antibiotics are released into the environment from production sites, contributing to the growth and spread of antibiotic resistance. Companies have an obligation to keep this issue in mind and to set requirements for suppliers and subcontractors concerning environmentally sound water management.

Energy

Reducing energy consumption is both profitable from an economic perspective and positive from a sustainability perspective. **Investments that reduced a company's energy consumption are often more profitable even in the short term.** It is also important that the **energy used comes from renewable sources.** As a manufacturer, one option is to **develop and supply products that use less electricity.** This has become an increasingly crucial issue, as the overall energy consumption in healthcare has decreased while the number of medical technology (MedTech) devices has increased. Today's MedTech equipment represents a significant part of energy consumption in healthcare, and many measures are being taken to reduce it. Issues being debated include energy efficiency requirements and the ability to measure data – and possibly even provide it in real time.

2.4.2 Social issues

Healthcare as a societal function is embedded in the social dimension of sustainability, so there are many social issues inherent in its broad system context. Two universal principles underpin global healthcare: 'leave no one behind' and 'do no harm'. The first refers to the need to ensure healthy lives and to promote well-being at all ages, with the aim of achieving universal health coverage and equity. The second principle relates to the healthcare system and the caregiver to caretaker dynamic, where the risk of harm should be weighed against the potential for improvement.

Social determinants are defined by the WHO (Social Determinants of Health, 2019) **as the non-medical factors that influence health outcomes.** They can be broken down into two main areas of importance and impact: who has access to healthcare in relation to the need for healthcare – and the actual success and outcomes of healthcare activities. Up to 55% of health outcomes have been identified as depending on social aspects.

There are three main categories that can have a significant positive impact on sustainable development in healthcare: **prevention, procurement and people.** Each of these categories relates to strengthening both individual and organisational capacity – in order to minimise the need and demand for services and products that have negative social or environmental impacts. Different types of social issues relate to the main social aspects of healthcare, including health, accessibility, income, inclusion, non-discrimination, education, working conditions and the working environment – both within and around healthcare facilities, as well as in the supply chains of actors in the ecosystem. Some of the key issues concerning working conditions and working environments are presented in the following chapters:

Working Environment

Employees are often the key resource in an operating business, and a good working environment is a prerequisite for good performance. Offering employees favourable working conditions and terms for employees makes a company more attractive. This in turn strengthen a company's brand and makes it more competitive.

Some countries, such as the Nordic countries, have comprehensive legislation in this area that sets higher standards than most other comparable countries. This means that companies operating in such a legislative context have already made headway in their systematic work for a good working environment, simply by complying with rules and regulations. Many other European countries have set up similar regulatory frameworks which cover most types of jobs and working conditions.

Risk assessment

The strategic work of creating a good working environment often starts with risk assessments of the business and operations. This can include assessments of everything from physical risks such as crush injuries, toxic chemicals, monotonous movement and ergonomics – to more psycho-social issues such as stress, influence, bullying, discrimination, etc. From a starting point in such assessments, it is possible to develop routines, objectives and targets and action plans to form a strategic work on the working environment. A management system such as ISO 45001 could be an appropriate support for this strategic work.

Social work environment

Social and organisational working environment has become an increasingly important part of strategic work on a good working environment in general. No one should feel left out or discriminated against because of their gender, ethnicity, religious beliefs or sexual orientation. On

the contrary, diversity in the workplace should be seen as an asset, especially in today's globalised marketplace where the ability to understand and apply different perspectives is becoming increasingly valuable.

Working environment in supply chains

Working conditions and the working environment are also an important area to monitor and evaluate when it comes to a company's value chain, with suppliers and subcontractors. Many products in the life sciences industry are manufactured in countries with regulatory frameworks and traditions that are very different from those in Europe. **Companies have an obligation to live up to minimum standards of international conventions and guidelines on working conditions,** such as the ILO conventions on core labour standards (International Labour Organisation, the UN body responsible for ensuring accessible, productive, and sustainable work worldwide).

Working conditions and the working environment are **a natural part a company's external code of conduct.** A code of conduct includes requirements to comply with ILO conventions on fundamental rights, safety – as well as conventions on forced labour, child labour, workers' rights to organise, and so on. In certain countries, migrant workers are often used in inappropriate ways, so these conventions should be taken into account. If there is a risk that international conventions and rights are being violated, on-site inspections and audits should be carried out.

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3

A path to sustainability through MedTech product development

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3.1
Introduction to Sustainable Design in healthcare

Sustainable healthcare is not a universally established and shared concept, nor is there a clear path for moving the healthcare sector towards sustainability. Today, different approaches address methods and processes that enable health systems to meet the healthcare needs of individuals by achieving optimal health outcomes while responding to current and future cultural, social, and economic conditions (Prada, 2012). Despite different definitions of sustainable healthcare systems and different attitudes towards sustainability, "all approaches seem to have in common that a comprehensive approach with a long-term focus and a need to balance economic, social, and ecological interests needs to be used in the discussion of sustainable healthcare systems." (Fischer, 2015, p. 298).

It is also important to remember that the term sustainability is derived from the verb "to sustain", i.e., "to maintain", "to endure": to be sustainable is to be able to live within the load capacity of the system we are part of. Sustainability is, first and foremost, a strategic balance that requires our care and commitment but provides us benefits in the short, medium and especially in the long term. This is true when we consider the impact on personal health and well-being, but also on industrial strategies. Achieving an integrated view of sustainability necessarily means looking at longer time horizons. This does not exclude the short term; on the contrary, it means reading short-term strategies in the light of medium- to long-term planning.

From this perspective, the design phase is crucial. According to various studies, 80% of the environmental impact of the products, services, and infrastructure around us is determined at the design stage (Thackara, 2005). Although it is one of the most intangible and least impactful phases in terms of consumption and emissions, the design stage is where the impact of products can be analysed, predicted and addressed.

3.1.1 From EcoDesign to design for sustainability

Over the years, EcoDesign has been a common term used to define an approach to industrial design with a specific focus on the environmental requirements of products throughout their life cycle. Despite some initial successes, this approach has shown relevant shortcomings (Ceschin & Gaziulusoy, 2016): first, the lack of complexity needed to address systemic problems, such as the sustainability of a MedTech device. Second, the narrow focus on efficiency and environmental criteria: once the inefficiencies and 'bad design' are removed from products, the benefits are marginal and increasingly costly. The risk of an EcoDesign approach is therefore to invest resources in addressing minor sustainability problems.

For this reason, it is preferable to talk about **Design for Sustainability,** which encompasses a range of approaches and methods that, in general, abandon the product-centric focus of Green and EcoDesign and pay greater attention to system-level changes (Ceschin & Gaziulusoy, 2019). This is reflected in two main evolution trends of sustainability innovation (Adams et al., 2016):

- From technology to people innovation: Design is moving from an incremental, technically focused approach to innovation, towards sustainability innovations that incorporate the social dimension, focusing on users and behaviour change.
- From insular to systemic innovation: Design is evolving from innovations that address a company's internal issues towards a focus on the wider socio-economic system, which includes but goes beyond a company's boundaries, involving a wider network of stakeholders.

Overall, designing for sustainability means envisioning scenarios of production, use and reuse that are compatible with the present by designing solutions that take into account the different dimensions and stakeholders of the value chains involved. An integrated approach to sustainability usually includes three dimensions:

- **Environment:** adopting sustainable practices to reduce the environmental footprint of a product.
- **Society:** being responsible for all the people involved throughout the value chain.
- **Economy:** being economically viable and competitive in the marketplace.

In the 1960s, Bruno Munari (1963) used the term **good design,** which best represents this concept: we should not consider sustainability as a list of social or environmental criteria to be met, but first and foremost as a well-done project, a 'good design' that best combines the interests of business, society and the planet.

Table 3.1: *Sustainability principles and guidelines*

Sustainability principles	Guideline questions	
 **Profit** **Goal: Distributive Economic Sustainability**	**Is the project replicable?**	What economical efforts are required? What cognitive efforts are required? What is its potential scale of diffusion?
	Are the proposed solutions cost-effective?	How much is the saving in the production phase? How much is the saving in the consumption phase? How much is the saving in the disposal phase? Are the external costs taken into account?
	Is the know-how shared outside of this project?	Is it possible to share knowledge about the current state of the art? Is it possible to share the design process steps? Is it possible to share the final results? Is it possible to share the final data of products/ services? Are data, studies, reports and good practices provided as open-access?
 **Planet** **Goal: Systemic Quality**	**What is the contribution of the project to the reduction of environmental impacts?**	How much does the system reduce the waste production? How much energy does the system save? How much water does the system save? How much raw materials does the system save?
	What are the main benefits for the environment?	How much can the system reduce air emissions? What are the benefits for the local territory? What are the benefits for the territories in which the system's components are produced?
	Does the system promote systemic awareness?	Is the linkage between man's health and planet health promoted? In what way?

Sustainability principles	Guideline questions	
 **People** **Goal: Centrality of the Person**	**Who benefits from the project results?**	What impact has the system in the societies Where the system's components are made? What impact has the system on chronic patients? What impact does the system have on healthcare staff? Will the project's results harm anyone?
	Does the system promote sustainable behaviours?	What cognitive efforts are required to patients? What cognitive efforts are required to healthcare staff? Are popular channels used for disseminating the project?

In addition to the sustainability dimensions, it is important to consider the main scope of design. As we have seen, design for sustainability encompasses many approaches, each with its own recognised methodological background (Ceschin & Gaziulusoy, 2019). However, to simplify, **we can refer to three levels of design scope: product, service, and system** (Figure 3.1). In all three levels, designers should always consider the entire life cycle of a solution and the impact on different stakeholders. Still, they focus specifically on one of these three levels.

Product design focuses on the product level, considering sustainability aspects related to materials, shapes and volumes, and product usability, but also looking at the supply, use and disposal processes. This includes approaches such as Design-for-X and Circular Product Design.

Service design focuses on the service level, including products of course, but mainly looking at the possibility of new business models oriented towards the benefits of using products rather than purchasing and owning them. In the area of sustainability, various strategies for product sharing and remanufacturing are emerging, as well as digital cloud systems.

Finally, **systemic design** addresses the system level, analysing the flows of materials, resources, by-products and information that make up a socio-industrial system and the value chain behind it. In this case, we design processes and strategies that link different production systems to create new business models.

In the MedTech sector, it is clear that the product level is the first of the three levels examined to be addressed. Of course, the complexity of biomedical devices affects the scope of design: simpler devices require a more product-focused vision, while medium- to high-complexity devices require solutions that are more service- and system-focused. In this chapter, we look at sustainability approaches in product design, while systemic design strategies will be explored in the next chapter.

3.1.2 Circular Product Design in MedTech

Whether it is a simple disposable device or complex biomedical equipment, the design phase always has to address key aspects related to the product's performance, usability and sustainability.

In the 1990s, a few pioneering companies experienced the benefits of 'concurrent engineering', a life cycle design approach aimed at increasing efficiency and performance while optimising costs and development time. This approach introduced several tools that fall under the umbrella of Design-for-X (DfX), where 'X' refers to different properties related to one or more aspects of the process: manufacturing, quality, reliability, assembly, but also new environment-oriented methods related to the disassembly and recycling of industrial products (Kuo, Huang & Zhang, 2001). As

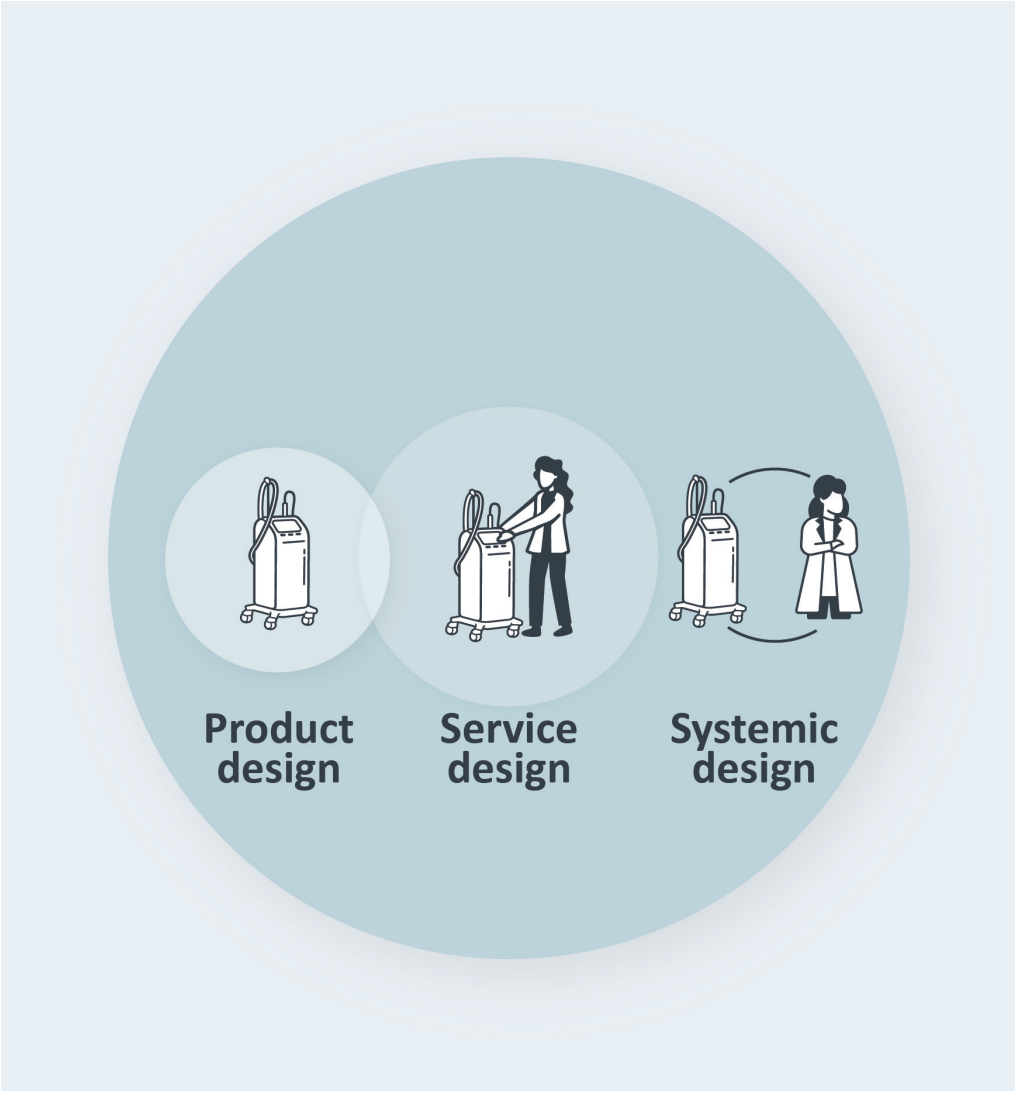


Figure 3.1: *Visualisation of the main scopes of design*

discussed above, during the same period, industrial design introduced the EcoDesign approach, which, like DfX, aimed to bolster business competitiveness in response to the growing demand for environmental performance, though still with a limited approach to product sustainability (Cruel, Diehl & Ryan, 2009). Even if both approaches showed the weakness of a narrow focus on end-of-life, the concepts of disassembly and maintenance are still key assets in the current debate around product longevity, which has been reintroduced by new circular economy models (Cooper et al., 2015). In particular, **Circular Product Design includes strategies that support designers and manufacturers to improve the long-term sustainability performance of their products** (Mestre & Cooper, 2017). The guiding principle is "designing waste": placing the product in a circular economy where the value of the product, its components, and materials are retained and not wasted, with the aim at overcoming the take-make-waste linear economic model. This shift towards Circular Product Design is contextual: products are not single events to be made more sustainable, but are designed in the context of their technological, social, and economic system (Pereno et al., 2021). In this perspective, the recycling of products and materials is overtaken by new strategies for "closed loop value recapture" (Crul, Joore & Celik, 2019), based on maintenance, reuse, and refurbishment. This new perspective brings two new outcomes: the first is a broadening of the design approach from the product to the system which it is set in. The second is a renewed focus on components and product disassembly, which becomes a priority in circular business models.
The adoption of Circular Product Design strategies is spreading across many manufacturing sectors. Although historically less targeted by environmental standards and concerns, MedTech product development is also changing and is slowly but surely seeing a growing interest in sustainability and circularity.

3.1.3 Sustainable MedTech product development

The evolution of purchasing models for goods and services towards greater collaboration between public or private customers and suppliers can facilitate inclusion of environmental and social sustainability criteria in procurement processes. However, the European landscape shows that MedTech companies suffer from a widespread lack of knowledge about sustainable design. **Well-established strategies in other manufacturing sectors, from design for reduction to design for disassembly, can easily be transferred to the healthcare sector,** but this requires training of MedTech designers. On the other hand, design strategies related to the experimentation with innovative sustainable materials face huge obstacles, as MedTech is a highly regulated sector subject to stringent protocols.

In addition to sustainable design strategies, other design methods can bring important benefits in terms of both innovation and sustainability. Co-design tools and methods can effectively involve healthcare professionals and patients in the definition of innovative products that combine efficiency with usability and sustainability, with the aim of improving healthcare treatments and ease of use by different categories of users (Rajkomar, Mayer and Blandford, 2015).
As discussed above, the application of Circular Product Design to healthcare deeply involves biomedical devices. Strategies that could be implemented in MedTech product development essentially follow the European Waste Framework Directive (Figure 3.2), which sets priorities in waste management, moving from prevention to disposal in the landfill as a last resort.

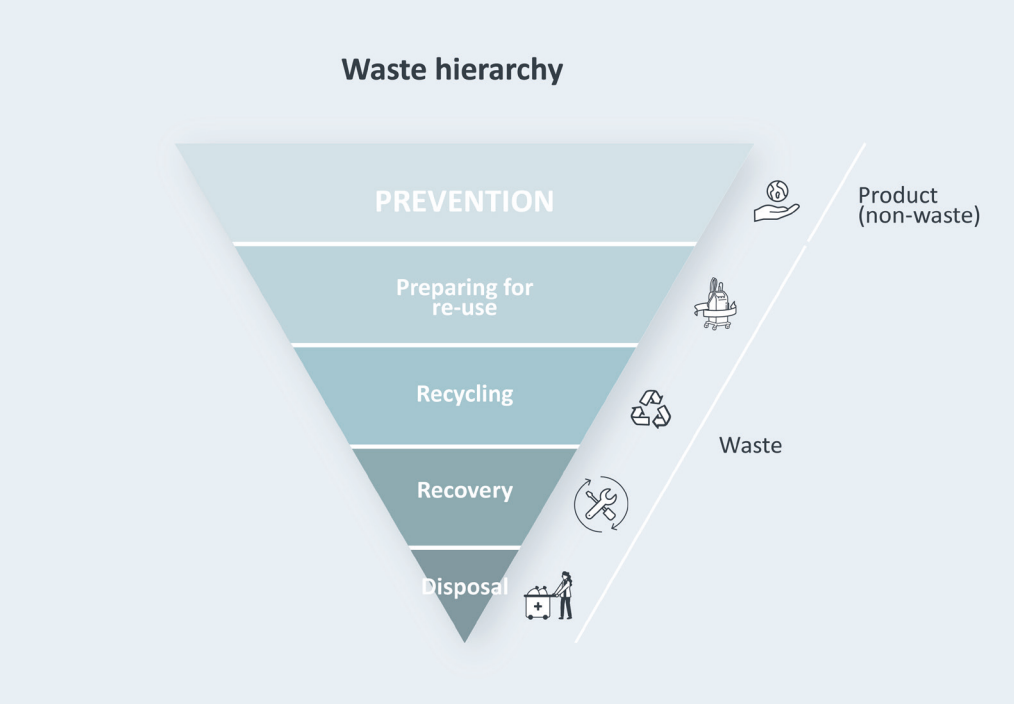


Figure 3.2: *Waste hierarchy, adapted from the Waste Framework Directive by the European Commission (2008)*

Priorities guide the designer's choice but must be balanced against the features of a MedTech product, particularly the level of complexity and contamination. Therefore, **remanufacturing and reuse are the main strategy for medium- to high-complexity medical devices,** while low-complexity devices that are more difficult to clean (e.g., intravenous catheters, tubes, syringes, needles) are prioritised for design strategies that favour their recycling. Shifting current supply and consumption patterns towards the reuse of medical devices will require some major changes by all the actors involved (MacNeill et al., 2020). First, a linear system minimises liability and complexity for hospitals and healthcare facilities, as the adoption of single-use products is a relatively simple way to reduce the possibility of human error in managing reusable devices. However, the environmental and economic benefits of remanufacturing can be achieved without radical changes, e.g., by outsourcing the management of the device collection, storage and remanufacturing process to third-party providers to minimise both liability and the required infrastructure. Second, current business models incentivise single-use devices over reusable alternatives, as they aim to maximise profit through high volume sales driven by consumption. However, there are **several effective circular business models for medical devices** (Guzzo et al., 2020) that are mainly based on improving the performance provided, such as servitisation models, where the manufacturer sells the service or device function, together with service packages that provide ongoing support, maintenance and training. This type of offering can be particularly attractive and beneficial to healthcare facilities. Finally, the role of legislators and policymakers is crucial in providing clear and consistent guidelines on the reprocessing of reusable devices, reducing the confusion and complexity of the standards to be followed, and avoiding that the choice of single-use devices is motivated by greater certainty of regulatory compliance.

3.2
MedTech product and packaging strategies

The strategies for sustainable MedTech product development are manifold and depend heavily on the nature of the product design. However, it is possible to identify recurring trends and guidelines that can steer designers in approaching design for sustainability.
In the following paragraphs, we will examine in detail two macro-approaches that are key to this manufacturing sector and to Circular Product Design:
The **Design for reduction** approach works on the steps upstream of the production process, addressing issues such as the supply and use of resources and materials, and the implementation of digital technologies.
The **Design for the life cycle** approach focuses on end-of-life management to anticipate new recycling and especially reuse scenarios.

3.2.1 Design for reduction

The overall goal of a Design for Reduction approach is to minimise resource consumption and waste generation at all stages of the product life cycle. Reducing means not only using less material, but also implementing a set of design strategies to improve the optimisation of resources and processes. These include selecting materials according to their use and disposal requirements, preventing upstream waste generation and finding technological solutions that 'dematerialise' both production and use.
The benefits are both environmental and economic, as a reduction approach optimises the supply and use of resources, which in most cases brings production and logistics benefits. Waste reduction lowers environmental impact and disposal costs, which is a benefit to end-users who manage waste, especially hazardous or infectious waste, but also a competitive advantage for the manufacturer.
Design for reduction strategies can be divided into four main areas, as also shown in Table 3.2.

Reducing materials and volumes

This strategy mainly focuses on designing products and services that use less material per unit of production and during their use. Material reduction has a positive impact on all stages of the life cycle: the extraction of raw materials is minimised, manufacturing processes are designed to use less material, the consumption of such products has a lower impact, and the disposal phase has less waste.
From this perspective, the following design aspects should be given particular attention:

- **Thickness.** A proper ergonomic approach can ensure the same usability and effectiveness while reducing product thickness. For example, the design of ribs or frames can stiffen the structure while reducing the overall thickness.

- **Volumes.** In the healthcare sector, a small reduction in materials can have huge positive effects when considering the waste produced by hospitals. In particular, ancillary products such as packaging are often oversized compared to their actual functional requirements: new shapes or more appropriate materials can reduce packaging volumes.
- **Miniaturisation.** Throughout history, the use of new technologies has enabled manufacturing to miniaturise products and components. Possible alternative technologies should always be explored and assessed to support material reduction. In particular, digital technologies can play a key role in dematerialising information and supporting materials.
- **Scraps reduction.** Reduction strategies consider not only products, but also materials that are discarded during manufacturing processes. This is particularly relevant for products whose size, shape and volume are determined by strictly technical parameters, such as prostheses or surgical devices. Advanced technologies, such as additive manufacturing, can also help reduce scrap and waste production.

Increasing efficiency

Reduction strategies can be applied throughout the life cycle, especially in production. For example, advanced high-efficiency manufacturing technologies can reduce energy and resource consumption. **This means decreasing the embodied energy of a product** – i.e., the energy required over its life cycle – or its ecological rucksack – i.e., the total amount of materials taken from nature to make a product, minus its actual weight In order to reduce these indicators, it is also important to consider logistics by identifying **packaging, transport, or warehouse management solutions** that are more efficient in terms of resource consumption.
Digitalisation also contributes to reducing the amount of energy and material consumption while increasing a company's efficiency. **Shifting from physical supports to digital management systems** is a key step and an advanced 'Industry 4.0' logic can optimise manufacturing processes and reduce resource consumption.

Precycling

Preventing waste from being produced is obviously better than treating or cleaning up waste after it has been created. This is not always possible, but 'precycling' strategies specifically aim to **prevent waste by avoiding items that could be unusable for end users or whose short life cycles will generate a huge amount of waste.**

In healthcare, many biomedical products have an ultra-short life cycle. In some cases, the use of

disposable products is essential even if their life is very short, while in other cases, waste can be avoided. For example, pre-assembled kits for patient medication or transfusion treatments are unlikely to meet all needs, and many disposable products are not used but have to be disposed of anyway. Modular kits can allow end users to customise products according to their routines and needs, so they can unpack and use only what they actually need. Packaging also has a very short life cycle and requires design strategies to reduce or even avoid it altogether.

Dematerialisation

A careful analysis of user needs can enable a **shift from ownership to use and thus from a product to a service level.** This may require a change in business model as well as a shift in product manufacturing.

Service-based models may **require MedTech products to be designed for more intensive use by different users** or to be easily transported from one place to another. This is the case, for example, when we propose sharing equipment between different healthcare facilities. From an environmental perspective, service-based models reduce the number of product units, which helps to cut resource and material consumption. In addition, service management requires monitoring of the product life cycle and the relationship with users. With this in mind, digital systems help to dematerialise processes and communications according to new business and production models.

3.2.2 Design for the life cycle

The design stage can impact the sustainability of an entire product or service life cycle. Indeed, design strategies for the life cycle aim to 'close the loop' by pursuing product regeneration. This includes a wide range of solutions: energy recovery from medical waste is probably one of the most common strategies today, but it is one of the least preferable as it only increases the energy-generating capacity of waste and does not fully tap the potential of products and materials. The most preferable strategies are the recycling of materials and especially the reuse or remanufacturing of products or their components.

Design for life cycle can be divided into three macro-strategies, which in most cases are alternatives. In principle, **the selection criterion is the embedded complexity of a MedTech device:** a cheaper, simpler product should be designed for recycling, a complex device for reuse, and a product that will become hazardous or special waste at the end of its life can be optimised for disposal or energy recovery.

Facilitating waste sorting

The first important aspect is to **support end users in identifying the type of material and waste.** Often a nurse or a caregiver has little time to decide how to sort waste. In some cases, it is clear which waste is infectious or hazardous, but sometimes recyclable waste may be improperly disposed of. This is not only an environmental problem, but it also has huge disposal costs for a health facility.

From a design point of view, it is **important to correctly identify materials by adopting standard symbols.** The **separation of different components** should be facilitated, especially when parts of the device are in contact with biological fluids while others are not. These measures make it possible to choose landfill or energy recovery only for waste that cannot be regenerated.

Promoting value retention

Many, if not most, biomedical devices are made from a variety of materials. Material diversification is usually driven by technical requirements: complex biomedical devices need to perform different functions and require several materials. In other cases, simpler products combine different materials for economic reasons or, often, due to design habits. For example, biomedical packaging typically combines layers of paper and plastic because paper printing used to be more cost-effective, but is no longer so. However, **material diversification can seriously hinder the recycling of devices and packaging,** as it requires more effort to separate the components at the end of their life cycle. **Using only one material or reducing the number of materials is a preferred option.** This also includes using different types of plastic, which can make separation and sorting more difficult at the recycling stage. **If more materials are needed, a design for disassembly approach is recommended** (Cooper et al., 2015), as it "focuses on how to design easily disassembled products; meaning that the parts and materials can be easily and economically separated. The possibility of easy separation of the parts facilitates the maintenance, repairs, updating and remanufacturing of the products" (Vezzoli & Manzini, 2008, p.181).

Design for disassembly not only improves component recycling but also brings technical and economic benefits in terms of product maintenance and upgrades. This requires a preliminary study of the component system. There are various analysis methodologies, such as HotSpot Mapping for product disassembly (Flipsen et al., 2020). All methods aim **to define the hotspots for product maintenance and the separation of different components and materials, taking into account the technological effort required.**

In general, there are three main points to consider:

- If possible, avoid welding, extra-strong adhesives or other joining systems that prevent easy separation of different materials.
- Consider the possibility of using non-chemical technologies to separate components in complex products (e.g., aeraulic selection and separatiion);
- Design components according to their durability and ordinary maintenance.

Encouraging re-manufacturing

Remanufacturing is the process of bringing used products to a "like-new" functional state with a warranty to match (Matsumoto & Ijomah, 2013). It is considered **one of the core strategies of the circular economy in manufacturing,** as it allows us to extend the life cycle of products and reuse components with high quality, while reducing energy demand by up to 80%, depending on the product type (Gutowski et al., 2011).

Typically, **remanufacturing strategies are embedded in new service-based business models** that create a 'sustainable loop' of actions (Figure 3.3):

1. *Establish a collection system of end-of-life products.* This can focus only on a company's own end-of-life products or be extended to the same type of products from different companies.
2. *Inspect and select products that can be remanufactured.* Different refurbishment paths can be created depending on the type of product and its conditions.
3. *Disassemble the product.* This step deeply varies greatly depending on the function and complexity of the devices.
4. *Recondition, replace and reassemble.* This series of actions results in the creation of new remanufactured products.
5. *Carry out quality control and testing phases.* Remanufactured products should be safe and effective as the original ones, and a warranty is usually required.

Sanitisation or sterilisation are important steps that can be carried out at different times, and also several times, depending on the type of MedTech product.

Any high-value product can be remanufactured. However, **specific product design strategies should be implemented to make this process smoother and more effective,** as shown in Table 3.3. Therefore, design for remanufacturing focuses on some key design issues (Nasr & Thurston, 2006).

Figure 3.3: *The product/service life cycle and the remanufacturing loop of actions*

- Design for disassembly benefits remanufacturing strategies by facilitating the separation of different components to maintain their 'fitness for reuse'. Therefore, assembly methods should allow for non-destructive disassembly and reassembly. Minimising the number of connectors or choosing reusable connectors can facilitate this task.
- Design for multiple life cycles means increasing product reliability and durability to improve the restoration and cleaning processes required to remanufacture a product.
- Modular design is essential, which means designing functional clusters of components with similar technical (durability) and market life (technology change rate). Also, the choice of durable materials is important when designing for remanufacturing.
- Easy access to wear parts is important to support maintenance and facilitate remanufacturing by replacing the most critical components.
- Cleaning and sanitisation are fundamental for MedTech products, so opting for easy-to-clean shapes and materials is essential throughout the life cycle.
- The final design issue is feedback. The first level of feedback is about product support for take-back decisions, i.e., tools and procedures for monitoring the use and embedded condition of a product. The second level is about establishing feedback loops about products and remanufactured products to gain knowledge from other life cycle stages and stakeholders involved (Lindkvist Haziri, Sundin & Sakao, 2019). Since each complex device has its own specific features, establishing feedback protocols within the remanufacturing process can really improve product design.

Table 3.2: Reduction strategies for MedTech products and services

Design for reduction strategies

Reducing materials and volumes

designing products and services that use less material per production unit, as well as during their use

Volumes:

a small reduction of material can provide huge positive effects

Thickness:

can be reduced, ensuring the same usability and effectiveness

Miniaturise:

use of new technologies has enabled to miniaturise products and components

Scraps reduction:

reduce materials that are discarded during manufacturing processes.

Increasing energy efficiency

reduction strategies can be applied to the whole life cycle, especially within production. For example, advanced high-efficiency manufacturing technologies can lower energy and resource consumption

Precycling

preventing waste by avoiding items not used by end users or whose short life cycle will generate a huge amount of waste

Dematerialization

shifting from possession to usage, thus moving from a product to a service level.
This may require changing the business model, but also it demands a shift in product manufacturing. Service-based models may require MedTech products to fit a more intensive use by different users or to be easily transported from one place to another

Table 3.3: *Life cycle strategies for MedTech products and services*

Design for the life cycle strategies

Facilitating waste sorting

support end users in identifying the type of material and waste. From a design point of view, it is important to correctly identify materials by adopting standard symbols. The separation of different components should be facilitated, especially if parts of the device are in contact with biological fluids while others are not.

Promoting value retention

retain the value of a product within the economic system. This means using only one material where possible, or reducing the number of materials, or allowing easy disassembly of parts to facilitate maintenance, repair, upgrading and remanufacturing of products.

avoid welding, extra-strong glues or other joining systems that hinder easy separation of different materials

possibility of using non-chemical technologies for the separation of components in complex products

layout the components correctly according to their durability and maintenance

Re-manufacturing

bringing used products to a “like-new” functional state, it allows us to extend the life cycle of products and reuse components at high quality while reducing energy demand.

Usually, remanufacturing strategies are included in new service-based business models that establish a ‘sustainable loop’ of actions.

3.2.3 Packaging strategies

A special topic of interest in the context of MedTech product strategies is packaging, which protects and enables the safe transport and handling of biomedical products.

In almost all manufacturing sectors, **packaging is an essential but extremely critical item from an environmental perspective.** This is due to both the resources consumed for its production and to the essentially disposable nature of packaging, which results in high levels of waste generation over a relatively short life cycle. For this reason, **the latest EU Circular Economy Package paid special attention to packaging, particularly with regard to the use of plastics.** While other sectors have implemented design strategies aimed at reducing and optimising packaging from both a material and functional point of view, the healthcare sector pays less attention to packaging design. Undoubtedly, the need to respond to stringent regulations to guarantee maximum hygiene and/or sterility of products has led to a preference for plastic or composite materials as their physical-chemical characteristics make it easier to meet the standards imposed (Rizan et al., 2020). With this in mind, the design of packaging is exclusively aimed at safety during packing, transport and handling by healthcare professionals. In addition, the design of packaging communication is almost non-existent, and the role of communication is limited to conveying prescribed information.

However, the focus on packaging sustainability is also affecting the healthcare sector, and in the short term it will be imperative to rethink healthcare packaging from a functional and communicative point of view.

At a functional level, **packaging plays a central role not only in waste generation but also potentially in waste management:** hospitals often have very low rates of waste sorting, particularly of municipal solid waste from hazardous medical waste (Townend & Cheeseman, 2005), with considerable environmental and economic implications. In addition to management shortcomings, **the packaging of biomedical products is often difficult to separate, and the materials can be difficult to identify.** For example, Aarhus University Hospital has analysed its plastic packaging waste, which is the main recyclable type of hospital waste, and has found that most of the plastics were not identifiable and the remaining fraction consisted of 16 different plastics, both simple and composite. The hospital has therefore initiated a dialogue with more than 160 suppliers, which has led to greater uniformity and identifiability of plastic materials (Sookne, 2019). Packaging innovation is not just about improving existing packaging in terms of materials and volume, but can actively support system-wide change, as in the case of self-care and home care.

Many chronic disease treatments, such as haemodialysis, are moving towards home care to encourage greater patient autonomy: here, packaging can facilitate proper management of the treatment and the waste generated.
At a communication level, packaging has shown its potential in other sectors as a means of conveying messages and information: in healthcare, **packaging communication can actively support patient empowerment** in the self-management of care and help patients and healthcare staff to properly manage and dispose of waste.

Table 3.4: Sustainability guidelines for health and MedTech packaging

		PRODUCT	SYSTEM
MAIN GUIDELINE: Design the packaging together with the product, adopting a concurrent design approach to avoid additional environmental problems and costs during transport and storage.		●	●
REDUCTION	**Designing packaging and products with a view to optimisation of space and raw materials, reducing the volumes and materials.**	●	
	Optimize size and volumes. Avoid unnecessary oversizing, especially in secondary packaging.	●	
	Optimize materials. Reduce thicknesses and prefer lighter protective solutions, in order to minimise the use of materials.	●	
MATERIALS	**Preferring recycled, recyclable or biodegradable materials (where possible in accordance with the regulations and product requirements), facilitating post-consumer collection.**	●	
	Prefer, if possible, the use of materials that are easy to recycle Avoid, if possible, the use of composite materials and composite polymers.	●	
	Prefer, if possible, the use of materials that are biodegradable or compostable. Avoid, if possible, the use of plastics and materials difficult to recycle.	●	
	Better sorting of different materials. Avoid permanent joints and, if possible, prefer single-material pack and products.	●	
FLEXIBILITY	**Design the packaging/product so it can be easily customised and renewed without substantially changing the production processes.**	●	●
	Design a packaging adaptable to different types of products. Considering both sizes and communication.	●	●
LIFE CYCLE	**Design upstream the reuse of packaging after the consumption phase.**	●	●
	Reuse for the same or other application. If it is not possible to reuse the packaging for the same purpose, explore the possibilities of reuse in other sectors.	●	●
	Design packaging with multiple functionalities, thus extending its life cycle.	●	●
	Add new functions to extend the use of packaging. Providing functions able to make the use and/or reuse of the packaging easier.	●	●

		PRODUCT	SYSTEM
LITECHNOLOGY	**Use of new technologies to improve the sustainability of packaging.**	●	●
	Use of technologies able to monitor the entire life cycle. Increasing product safety and user awareness.	●	
	Use of technologies to provide information about product and end of life. Preferring low technologies that do not increase the environmental impact of packaging.	●	
SEMPLICITY	**Design the packing seeking simple shapes and essential graphics to prevent rapid semantic obsolescence.**	●	
	Prefer simple shapes. Take advantage of the shape to strengthen the visual identity and prevent semantic obsolescence.	●	
	Prefer simple graphics. Reduce and simplify graphcis, preventing semantic obsolescence.	●	
INFORMATION	**Design the packaging communication to encourage informed user choice both in the purchase and disposal phases.**	●	
	Provide clear and comprehensive information about product and packaging. Defer to external sources to avoid visual redundancy and confusion.	●	
	Improve the communication of the disposal. Provide information about materials and processes to facilitate waste sorting and recycling.	●	
USABILITY	**Ensure user-friendliness, avoiding unnecessary physical and cognitive efforts.**	●	
	Improve the affordance of product/packaging. Making it easy to open/close, use and dispose of it properly.	●	
	Guarantee an easy handling. During transport, storage and use.	●	

3.3
Social implications of production

The product design strategies seen so far mainly address environmental aspects, with social spin-offs related to increased usability for users and, in the case of new service-based models, a different approach to the use and ownership of biomedical products. However, **the social dimension is crucial in addressing the sustainability of the MedTech sector.** It is therefore necessary to move from the design to the production phase, examining the social implications that are crucial at this stage for a design perspective on the production, use and consumption models of MedTech products.

Production is often the most central process of business operations, especially for product-centred organisations. It is also the part of business operations that tends to have a large share of the environmental and social implications. Actual production, especially of products, comes with social impacts on those who supply inputs, those who produce, those who use the products and those who are, or think they are, affected by the production.
The social implications of production require a closer look at the social aspects of both the externalities and the external stakeholders affected, as well as the workers involved in in-house production. Business, and its operation and production, is part of a larger society and eco-system in which business and production both have potentially positive and negative social impacts.

3.3.1 The effects of production on local and global local society

Resource supply and production sites provide local jobs and contribute to the micro-economy and well-being of citizens, a social resource and partnerships within their community. Taxes and fees contribute to the economy and infrastructure, both of which benefit the surrounding community. Of course, implications may also be negative, for example where production poses threats to the physical health of people through waste, effluents, emissions and mining – or allows poor working conditions or even child labour.

Production sites – whether part of a company's own operations or outsourced – need to be accountable for the impact that production and distribution have on their local societal environment. Damage to the local environment in terms of pollution, effluents, waste, and spills or improper disposal of materials can have direct and indirect effects on the health and well-being of a community's members.

Climate change and air pollution are already considered major public health issues. The healthcare sector as a whole is a very carbon-intensive industry, accounting for about 5% of global greenhouse gas emissions. This means that **the sector can be responsible for bad health in some parts of society,** while promoting better health in others. The damage to health associated with pollution from production is estimated to be substantial. Yet many harms are difficult to pinpoint, and victims may be hidden or seemingly untraceable.

3.3.2 Health risks of products and production

Companies need to identify and manage health risks, as well as risks related to environmental impact, working conditions, human rights and anti-corruption – both internally and in their supply chain. Risks that may be hazardous to the local communities and stakeholders depend on a number of factors, including:

- **The types of material and substances use**d.
  - Electrical and electronic products containing hazardous substances and raw materials can increase such risks.
- **The number of components in a company's product.**
  - This can affect the complexity of the supply chain, and in what countries the components are being produced.
- **How much control a company has over production** and the ability to trace components.

3.3.3 Material selection

The selection of materials in a product is extremely important from a sustainability perspective. Ultimately, **material selection affects parameters such as life span and sustainability risks in the supply chain,** depending on the source and composition of a material.

Plastic is a material that is widely used in the life sciences industry, from MedTech products to packaging materials and pharmaceuticals. Depending on the type of plastic and input materials, the environmental impact can vary greatly. One example is PVC, which has been used extensively in a wide range of healthcare products, but has been gradually phased out from many applications in recent years. PVC is essentially a rigid plastic used in a huge number of products. Adding softeners to plastic gives it entirely different characteristics, making it suitable for use in tubing and ostomy and bloodbags, where it is used to this day despite the availability of substitutes. One of the most

widely used softeners is DEHP – Di(2-ethylhexyl)phthalate — which is toxic and harmful to reproductivity. Where plastics are used in products, it can be relevant to review the type of plastics used and consider using more environmentally friendly options.

3.3.4 Working environments

Apart from the social implications and issues that may impact the social surroundings of production – social issues are also apparent when looking at workers and their working environment. Employees are often a company's primary resource, and a **good working environment is a prerequisite for good performance.**
Providing employees with favourable working conditions and terms makes a company more attractive. This, in turn, strengthens a company's brand and makes it more competitive. Some countries, such as the Nordic countries, have comprehensive legislation in this area that sets more stringent requirements than those in most other comparable countries. This means that companies operating in such a legislative context already have made progress in their systematic work for a good working environment, simply by complying with rules and regulations. Many other European countries have set up similar regulatory frameworks that cover most types of jobs and working conditions.

3.3.5 Risk assessment

The strategic work for a good working environment often starts with risk assessments in the business and operations. This should be extended to subcontractors and the supply chain through procurement and other contracts. This may include assessments of everything from physical risks such as crushing, toxic chemicals, monotonous movement and ergonomics – to more psycho-social issues such as stress, influence, bullying, discrimination, etc.
Starting from such assessments, it is possible to develop routines, objectives and targets and action plans to carry out strategic work on the working environment. A management system such as ISO 45001 could be an appropriate support for this strategic work.

3.3.6 Social work environment

The social and organisational working environment has become an increasingly crucial part of the strategic work for a good working environment in general. No one should feel left out or discriminated against because of their gender, ethnicity, religious beliefs or sexual orientation.

On the contrary, **diversity in the workplace should be considered an asset,** especially in today's globalised marketplace where the ability to understand and apply different perspectives is becoming increasingly valuable

3.3.7 Managing the supply chain

Few operations have control of their entire value chain, both upstream and downstream. That is why it is important to consider what the boundaries of companies' sustainability work looks like. For most companies, this type of monitoring and control is limited to a few steps down the supplier and subcontractor levels. Responsibility in this sense could be described as reaching as far as possible, given what can actually be governed and controlled.

Investigating the nature and extent of impacts as far down the value chain as the extraction of raw materials often requires the organisation to be of significant size. However, **all companies can map their supply chains to the extent that they are able to do so. Based on this mapping, a risk assessment may be carried out** that includes those suppliers considered most likely to fall short in their sustainability work.
Businesses are advised to carry out risk and materiality assessments, as well as supply chain analysis, looking at social implications to ensure that operations and production do not harm citizens in the surroundings. At the very least, companies should make sure that all production and supply comply with domestic and international regulations and conventions on environmental and social responsibility, as well as accountability.

3.3.8 Working environment in supply chains

Working conditions and working environments are also **an important area to monitor and assess when it comes to a company's value chain,** with suppliers and subcontractors. Many products in the life sciences industry are manufactured in countries with regulatory frameworks and traditions that are very different from those in Europe. As a company, there is an obligation to comply with minimum standards of international conventions and directives on working conditions, such as the ILO conventions on core labour standards (International Labour Organisation, the UN body responsible for ensuring accessible, productive, and sustainable work worldwide).
Working conditions and working environments are natural parts of a company's external code of conduct.

A code of conduct includes requirements to comply with ILO conventions on fundamental rights, safety – as well as conventions on forced labour, child labour, and workers' rights to organise, and so on. In certain countries, migrant workers are often used in inappropriate ways, so these conventions should be taken into account. If there is a risk for violations against compliance with international conventions and rights, on-site inspections and audits should be carried out.

In a code of conduct, requirements for compliance with ILO conventions concerning fundamental rights, security – as well as conventions on forced labor, child labor, and worker rights to organize, etcetera. In certain countries migrant workers are frequently used in a unreasonable way, why such conventions should be paid attention to. Should the risk for violations against compliance to international conventions and rights, controls and audits should be carried out on site.

3.3.9 Supplier code of conduct

Establishing a code of conduct for suppliers and subcontractors is a way of taking responsibility for the value and supply chains that works for many organisations. A code of conduct describes the focus areas for suppliers to be accountable for, such as working conditions, environmental and human rights. Regulatory frameworks such as the UN Declaration of Human Rights, ILO conventions, REACH regulations, etc., can be integrated into a code of conduct. Suppliers need to sign the code to confirm that they are aware of, and comply with, its requirements. From this point on, it is important to monitor and control compliance with the code, especially if the supplier is located in an 'at-risk country'. For a small business, it may be too costly to carry out on-site audits. In such cases, it is possible to obtain help from specialist organisations that work with and collect results from different types of monitoring and control.

Industry perspective on sustainable MedTech design:

Insights from the BioPmed cluster (Italy)

Eugenio Mimosi, *Bioindustry Park 'Silvano Fumero'*

Sustainability has become a critical issue in all industries, and the medical technology (MedTech) industry is no exception. In recent years, there has been growing awareness of the environmental and social impacts of various industries, and the MedTech industry has been involved too. It is crucial that the MedTech industry considers its own impact and takes steps to minimise it.

One of the main reasons why sustainability is important in the MedTech industry is that it helps reduce the industry's environmental impact. Medical devices and equipment often require large amounts of energy and resources to manufacture, transport, and dispose of. This can have a significant impact on the environment, including air and water pollution, habitat destruction, and greenhouse gas emissions. By adopting sustainable practices, such as using renewable energy sources and minimising waste, the MedTech industry can reduce its carbon footprint and minimise its impact on the environment.

In addition to reducing its environmental impact, a sustainable approach can also help to improve the efficiency and effectiveness of medical technologies. For example, designing and producing devices that are more energy-efficient can reduce costs and improve patient outcomes. Sustainability can also help ensure that medical technologies are accessible and affordable for all individuals, regardless of their socio-economic status. This is particularly important in low-income and underserved communities, where access to healthcare and medical technologies can be limited.

Another important reason why sustainability is important in the MedTech industry is that it can help ensure the long-term viability of the industry. As consumers and regulators become increasingly concerned about the environmental impact of products and services, the demand for sustainable MedTech solutions is likely to increase. By adapting to this trend and embracing sustainability, the MedTech industry can stay relevant and competitive in the long term. This is important not only for the industry itself, but also for the people who rely on medical technology to maintain their health and well-being.

There are several ways in which the MedTech industry can meet sustainability requirements. One way is through the design and production of medical devices and equipment. By designing products that are energy-efficient and made from sustainable materials, the industry can reduce its environmental impact and improve the efficiency of its products. In addition, the industry can adopt sustainable manufacturing practices, such as using renewable energy sources and minimising waste, to reduce its environmental impact.

Another way in which the MedTech industry can embrace sustainability is through the disposal and recycling of medical devices and equipment. Many medical devices and equipment contain

hazardous materials that can be harmful to the environment if not disposed of properly. By implementing sustainable disposal and recycling programmes, the MedTech industry can minimise the environmental impact of its products and reduce the amount of hazardous materials that end up in landfills.

Finally, the MedTech industry can meet sustainability targets through its supply chain management. By working with suppliers that have strong sustainability practices, the industry can reduce its environmental impact and improve the sustainability of its products. Additionally, the industry can implement sustainable transportation practices, such as using alternative fuel sources and reducing emissions, to minimize the environmental impact of its products.

In conclusion, sustainability is an important issue for the MedTech industry. By adopting sustainable practices, the MedTech industry can reduce its environmental impact, improve the efficiency and effectiveness of its products, and ensure its long-term viability. In addition, sustainability can help ensure that medical technologies are accessible and affordable for all individuals, regardless of their socio-economic status. By taking action now, the MedTech industry can contribute to a more sustainable future for all.

Case study

Subject	E-ptfe polymer
Subject	Solvay SPA
Year	2020
Country	Italy

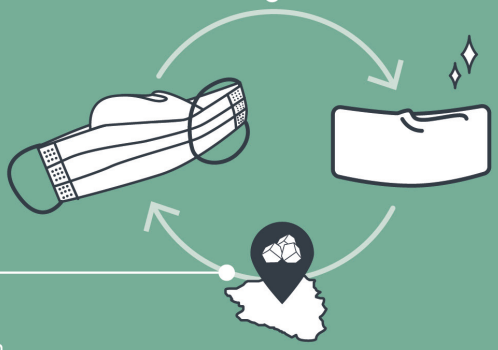
It is a new polymer for surgical masks filter that makes them reusable and shorten the supply chain by making it more independent from external markets.

less use of resources

less energy consumption

less waste produced

the **replacement of filters** reduces the consumption of resources as it allows the masks to be reused rather than remanufactured. This lowers the energy consumption required for production and also reduces the amount of waste produced.



less emission produced

the development of a more local supply chain increases independence from foreign markets for polymer production and shortens the supply chain, reducing emissions associated with **long transportation.**

Case study

Subject	Poligraf
Subject	TFC SRL
Year	2019
Country	Italy

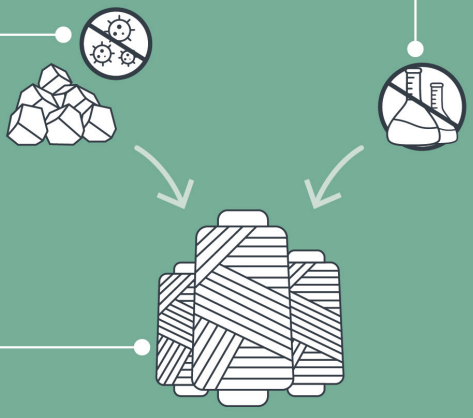
Poligraf is a series of fabrics with polygraphene yarn, which exploit the antibacterial properties of the latter, thus preventing the use of chemical additives. This avoids the impacts associated with the use of chemicals and optimises the life cycle of fabrics.

less emission produced

when fabrics come to an end-of-life, the absence of chemicals results in **lower emissions of harmful substances** into the environment. This also reduces the technical and economic effort for their disposal.

less pollutants

special chemicals are often required to make fabrics antibacterial. They provide such properties on a temporary basis, losing their effectiveness after a certain period of use or a certain number of washes. Poligraf, on the other hand, exploits the **permanent antibacterial properties** of this innovative material, **avoiding polluting chemicals.**



less waste produced

less use of resources

less energy consumption

the **increased durability** of these fabrics **extends their life cycle,** reducing waste production and the consumption of material and energy resources to produce new ones.

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4

Sustainability strategies in MedTech businesses

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The authors jointly discussed contents and equally contributed to the chapter writing. Silvia Barbero wrote par. 4.1 and 4.2; Hjalmar Bardh Olsson wrote par. 4.3.

4.1
Designing complex MedTech systems

4.1.1 MedTech as a complex system

Over the years, the definition of 'complex systems' has changed, even though we could describe a complex system as a whole made up of many interacting components that exhibit non-linear behaviour and are difficult to predict.
Indeed, in the 1940s and 1950s, cybernetics defined complex systems as having many interacting components that are capable of self-regulation. They emphasised the importance of feedback mechanisms and the ability of the system to adapt and evolve over time.
In the 1980s and 1990s, complexity science defined complex systems as consisting of many interacting components that, together, exhibit emergent behaviour. This definition highlighted the importance of understanding the emergence of new properties and patterns at the macro level resulting from the interactions of components at the micro level.

MedTech manufacturing, like other socio-economic and productive systems, can be seen as a complex system. Indeed, it involves a wide range of interacting components such as suppliers, manufacturers, regulators, distributors, healthcare providers, patients, and so on. These components are interrelated and interdependent, with each affecting the others in different ways.
Today's challenges are mainly related to the transition of healthcare to more sustainable models, complying with new and increasingly stringent regulations, and also meeting environmentally driven market demands. To meet these challenges, it is necessary to understand the complexity and interconnectedness of the different components of the MedTech manufacturing system and to address the various factors that influence the performance of medical devices.
This requires a systemic approach and the involvement of multiple stakeholders in the design, implementation and evaluation processes.

4.1.2 An introduction to systemic design

Systemic design is a holistic approach to design that aims to understand and address the relationships between systems, rather than focusing on individual components or problems in isolation (Sposito & Faggian, 2013). It emerged in the 1960s and 1970s as a response to the increasing complexity of social and environmental issues such as urban planning and sustainability.
Systemic design is closely related to sustainability as it aims to create solutions that are not only designed to have a good environmental impact, but are also socially and economically beneficial.
The approach is also in line with the principles of the circular economy (see section 2.2), which aims

to create closed-loop systems in which materials and resources are reused and regenerated rather than discarded.
By looking at the whole system, including the social and economic context, and involving stakeholders in the design process, systemic design can help create sustainable and circular solutions that address the interconnectedness of economic, social and environmental systems.

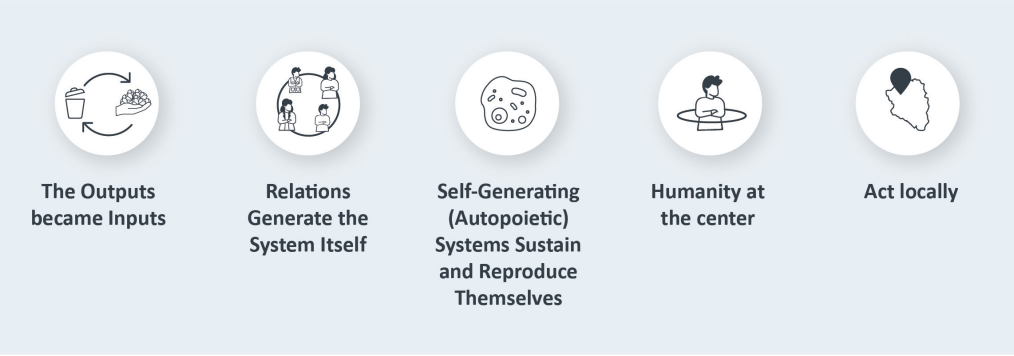


Figure 4.1: *The five principles of Systemic design*

As shown in Figure 4.1 pillars on which the systemic approach is founded are:

1. **The Outputs (Wastes) became Inputs (Resources) to Another One.**
   Inspired by the principles of natural processes in which there is no waste (the remains of one ecosystem become resources for another), this approach aims to create continuous flows of matter and energy. In fact, in contrast to the linear take-make-waste vision, this vision embraces a circular approach in which the waste from one process becomes the raw material for another. This closing of loops not only aims to achieve zero emissions, but also creates new jobs and a new economy through new processes and new products. Furthermore, the application of this principle to waste from the MedTech sector could have a particularly significant impact, as it could lead to a reduction in management costs and a redesign of the whole system (Barbero & Pallaro, 2017).
2. **Relations Generate the System Itself.**
   A system consists of a set of components in relation to each other. But each component is only strategic if it is related to another because it is the relationships that bring out the properties

that characterise the system itself. Therefore, in order to study a system, it is not possible to analyse a single node simply by taking it out of context, but one must always refer to the network of relationships that generate it.

3. **Self-Generating (Autopoietic) Systems Sustain and Reproduce Themselves.** Feedback mechanisms enable biological organisms to self-regulate and co-evolve with their changing environment. In this way, they are also able to sustain themselves by maintaining internal balances and external exchanges. Manufacturing facilities can be seen as biological systems that should be guided by these principles, seeking to regulate each other and then co-evolve together.
4. **Humanity at the center.** The user, with his or her needs and requirements, must be at the centre of any production process and, as he or she is only one node in a wider network of social, economic and cultural relationships, attention must also be paid to these, which constitute its context. (Bistagnino, 2011).
5. **Act Locally.** This means that, in redefining the relationships between the various actors in the system, the local approach is crucial because, by using local resources or addressing local users, it makes it possible to improve local development and combat the delocalisation of production and consumption, while also reducing the environmental impacts associated with globalisation (transport emissions, unsustainable exploitation of natural and human resources, etc.).

Therefore, systemic design takes inspiration from natural principles and applies them to the more practical context of economic, social and production systems, with the aim of reducing the consumption of local resources and developing more sustainable processes, minimising costs while increasing the efficiency of businesses, and promoting new businesses and new job opportunities. To achieve this, it follows a methodology (Figure 4.2) consisting of the following steps:

To achieve this, it follows a methodology consisting of the following steps:

1. **Holistic Diagnosis:** it is defined as a comprehensive mapping of the current context and its relationships through research, collection and processing of qualitative and quantitative data, conducted through desk and field research, with the aim of returning a visual output that is able to express the result of this analysis efficiently.

2. **Challenges and opportunities:** the mapping carried out in the previous step makes it possible to identify the challenges of the system, also thanks to a horizontal dialogue between actors from different backgrounds. The holistic perspective makes it possible to identify not only problems related to a specific element, but also those arising from the interaction of different components. Through more focused research, these challenges can be transformed into new opportunities through innovative solutions.
3. **Multi-criteria analysis:** once possible innovative solutions have been identified, they need to be selected through a context-driven multi-criteria matrix to select the most feasible solutions and prioritise them for integration into the new systemic design.
4. **Study of the outcomes:** before implementation, the effects that the new system could generate are studied in order to identify possible criticalities. The consequences of the project are studied both at the level of the components and at the level of the system, in order to define a set of realistic assumptions and quantitative/qualitative forecasts of the results generated by the shift from a linear to a systemic and circular model, from different points of view (environmental, economic and social), at different possible scales (micro, meso, macro) and time frames (short, medium and long term).
5. **Results implementation:** the final stage of the methodology is the implementation of the project, which nevertheless is not the end of the project. In fact, once the system has been implemented, the methodology provides for and incorporates into this step an iterative process that, through feedback mechanisms, allows the system to be improved in order to adapt to new changes in its context, evolving with it.
(Barbero S., 2016).

Figure 4.2: Visualisation of the Systemic design methodological framework

4.1.3 Systemic design for MedTech manufacturing

The complexity of the MedTech system - from packaging to products, services and policies - means that addressing just one of its components is not enough to significantly change the system and to make it more sustainable. Therefore, a systemic approach is needed to rethink the sector as a whole, proposing new design and economic models that **consider MedTech processes and products in their technological, environmental and social complexity.** This calls for strategies at both the product and system levels.

At the **product level** it is possible to:

- Adopt design strategies that have been implemented in other sectors and that can bring not only economic but also environmental benefits to manufacturers, such as:
  - Design for reduction, a strategy that aims to minimise the use of resources (both material and energy) by optimising volumes, maximising the efficiency of a product by reducing its embodied energy, avoiding waste or dematerialising wherever possible;
  - Design for the life cycle, an approach that aims to extend the entire life cycle of a product by facilitating the waste management of its components, retaining its value within the economic system or promoting its remanufacturing;
- Environmentally oriented decisions, such as favouring materials with low environmental and avoiding the use of chemicals.
- Implement co-design methods and tools to effectively involve healthcare professionals and patients in the definition of innovative products to increase their efficiency and usability.
- Adopt a logic of circular design of products to keep them in use as long as possible with a high value-added function, avoiding or delaying their disposal, through the regeneration or reuse of medical devices of medium complexity, the recycling of those of low complexity and/or difficult to clean, or closer dialogue with lawmakers to have a clear picture of the guidelines on the remanufacturing of reusable products.
- (Re-)design healthcare packaging from a functional, communicative and environmental point of view, facilitating the identification and sorting of different materials during disposal, and improving usability for all users, including the home care sector.

At the **system level,** it is possible to:

- Develop expertise in sustainable health care and raise awareness among colleagues and employees, including sustainable healthcare topics in hospital and company training, and provide training courses for health care workers and healthcare industry professionals;
- Monitor the environmental impact of your healthcare system and disseminate sustainability reports or data; implement corporate social responsibility and corporate social and environmental strategies to raise external and internal awareness; monitor environmental databases to map inputs, resource outputs and emissions throughout the supply chain.
- Pursue cost-effective and secure use of information and communication technology to support medical device manufacturing, with solutions such as eHealth for digital management and storage of health data, or TeleHealth for remote customer support.
- Consider all the sustainability aspects of a manufacturing business, not just those related to production, such as overall water and energy use in facilities, mobility and other welfare strategies that can improve sustainability, new spaces for research and experimentation in collaboration with other industries, customers and stakeholders.

4.2
New circular business models in MedTech

4.2.1 An introduction to circular business models

The slow adaptation of the healthcare industry to sustainability is one of the many challenges facing the sector (Ertz & Patrick, 2020). At the same time, healthcare itself, while essential to the well-being of the population, is a resource-intensive system (Guzzo et al., 2020). It generates large quantities of waste with a complex composition, including both non-hazardous waste and many different types of hazardous waste, which account for 85% and 15%, respectively, of the waste generated by the sector (WHO, 2018).

In this scenario, the circular economy approach aims to minimise waste by preserving the value of products and the materials from which they are made by keeping them in the economic system, either by extending the life of the products made from them or by 'looping' them back into the system for reuse (Hollander et al., 2017). Therefore, it could be a promising tool for a sustainable transition from the current linear paradigm of take-make-waste (Vence & Pereire, 2019).

In practice, the circular economy could be implemented by companies through business models that integrate circular economy principles into their value propositions throughout the value chain (Manninen et al., 2018).
Circular business models can be defined as business models that cycle, extend, intensify and/or dematerialise material and energy cycles in order to reduce resource inputs into, and waste and emissions from, an organisational system. This includes recycling, extending the use phase, intensifying the use phase and substituting products with services and software solutions (Geissdoerfer et al., 2020).
These models aim to minimise waste and maximise resource efficiency, creating a closed-loop system in which materials, products and components are reused, refurbished or recycled with significant environmental benefits. In doing so, they not only have a positive impact on the environment, but also generate economic benefits in terms of creating new economic opportunities, new market segments and financial savings through resource efficiency (OECD, 2012).

According to Geissdoerfer et al. (2020), **four general strategies for implementing circular business models can be identified** (Figure 4.3):

1. **Cycling:** keeping materials and energy within the system, through reuse, remanufacturing, refurbishment and recycling.

2. **Extending:** keeping the product in use as long as possible through durable and timeless design, marketing that encourages long periods of use, maintenance and repair practices.
3. **Intensifying:** increasing the use phase of the product, with solutions such as the sharing economy (Hamari et al., 2016).
4. **Dematerialising:** replacing physical supports with intangible solutions such as services or software, resulting in reduced consumption of material resources.
(Geissdoerfer et al., 2020)

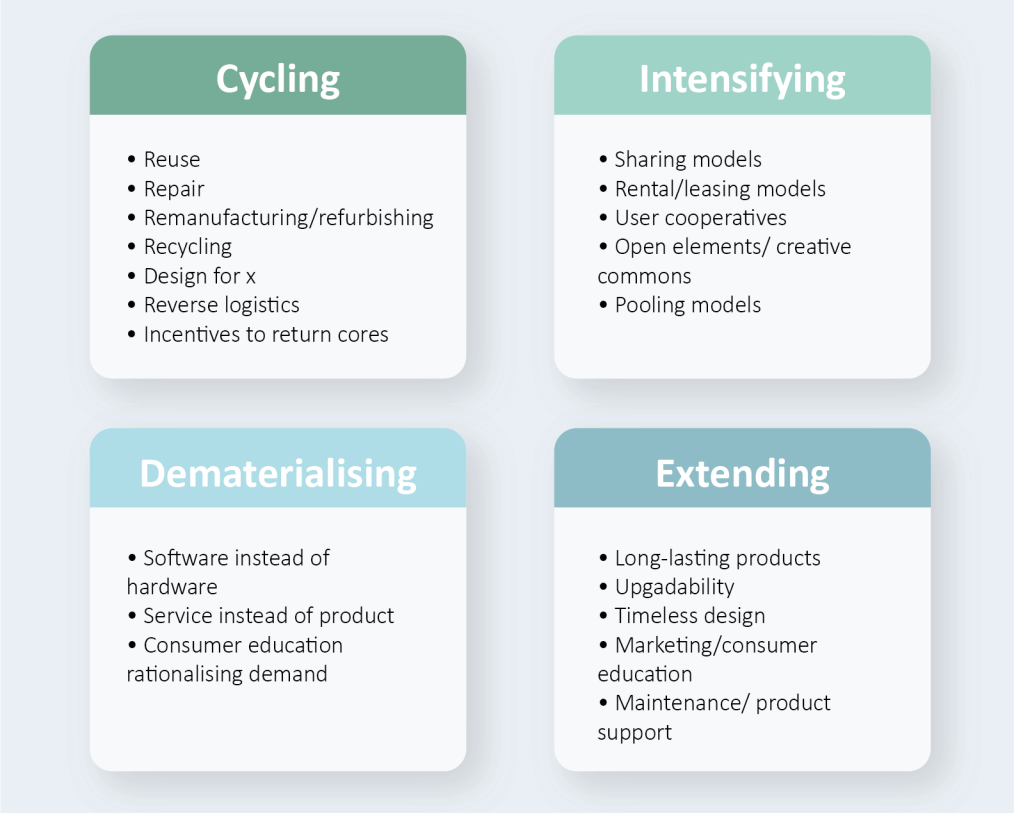


Figure 4.3: General strategies for implementing circular business models. Adapted from Geissdoerfer, 2020

4.2.2 Circular business model for the medical device industry

The business model perspective is useful from a sustainability perspective because it provides a practical framework for mapping and comparing different businesses through an equitable analysis (Ertz & Patrick, 2020).
To do this, it is necessary to include product value, which indicates the economic value of a functional product (Guzzo et al., 2020), as a criterion for analysis.
When dealing with medical devices, specific risk and safety regulations must be taken into account. Therefore, in addition to the **value of the product,** it is essential to consider its **criticality,** which represents the level of risk that a product poses to human health due to the nature of its contact with the patient (Guzzo et al., 2020), in order to approach a circular strategy in a coherent way. The study of circular strategies in terms of product value vs. criticality is therefore highly relevant to the design of circular business models in the medical device industry, also because criticality analysis allows a clinical view of risk to be added to an economic approach. (Guzzo et al., 2020).

For a first overview, we can identify four categories of medical devices based on the systematisation of the above criteria (Kane et al., 2018), as illustrated in Figure 4.4 and 4.5:

1. **Medium-to-high value, high-criticality devices.**
   Products for which product-integrated forms of recovery may be more appropriate due to the high value of the equipment, but for which recovery remains difficult due to the high criticality of their application.
2. **High value, non-critical products.**
   Products that do not require hygienic recovery with aggressive sterilisation and whose complexity and long life suggest remanufacturing and refurbishment strategies. This category includes products such as imaging equipment or large surgical devices, where design should focus on principles that facilitate refurbishment, disassembly, accessibility, cleanability, durability and maintenance, such as standardisation of parts or selection of durable materials.
3. **Low-value, high-criticality products.**
   Low-value products, such as single-use devices (syringes, bandages), which are characterised by low disposal and replacement costs and high recovery costs.

4. **Low-value, low-criticality products.**
Non-infectious products for which recycling would be the most appropriate strategy, but is often hampered by the fact that they cannot be distinguished from highly infectious products. Therefore, in addition to recycling, the strategy for their design should include principles facilitating sorting and disposal that can guide users to separate them properly.
(Kane et al., 2018)

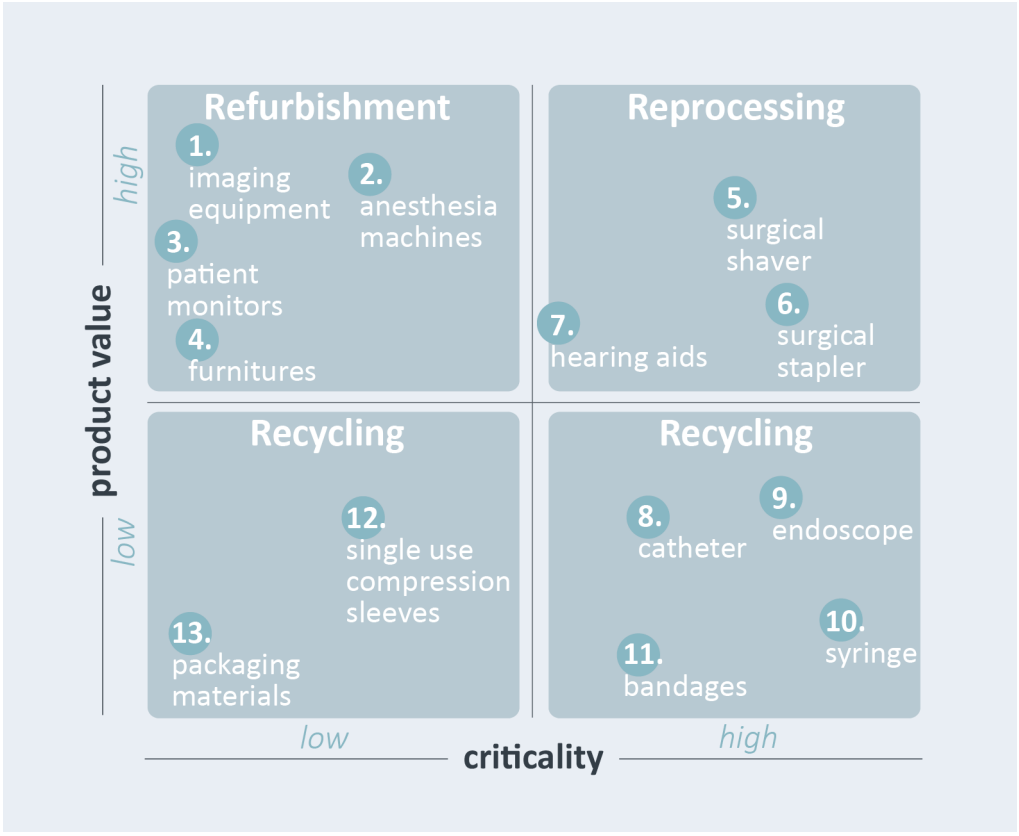


Figure 4.4: *Four categories of medical devices based on product value and criticality level. Adapted from Kane et al., 2018*

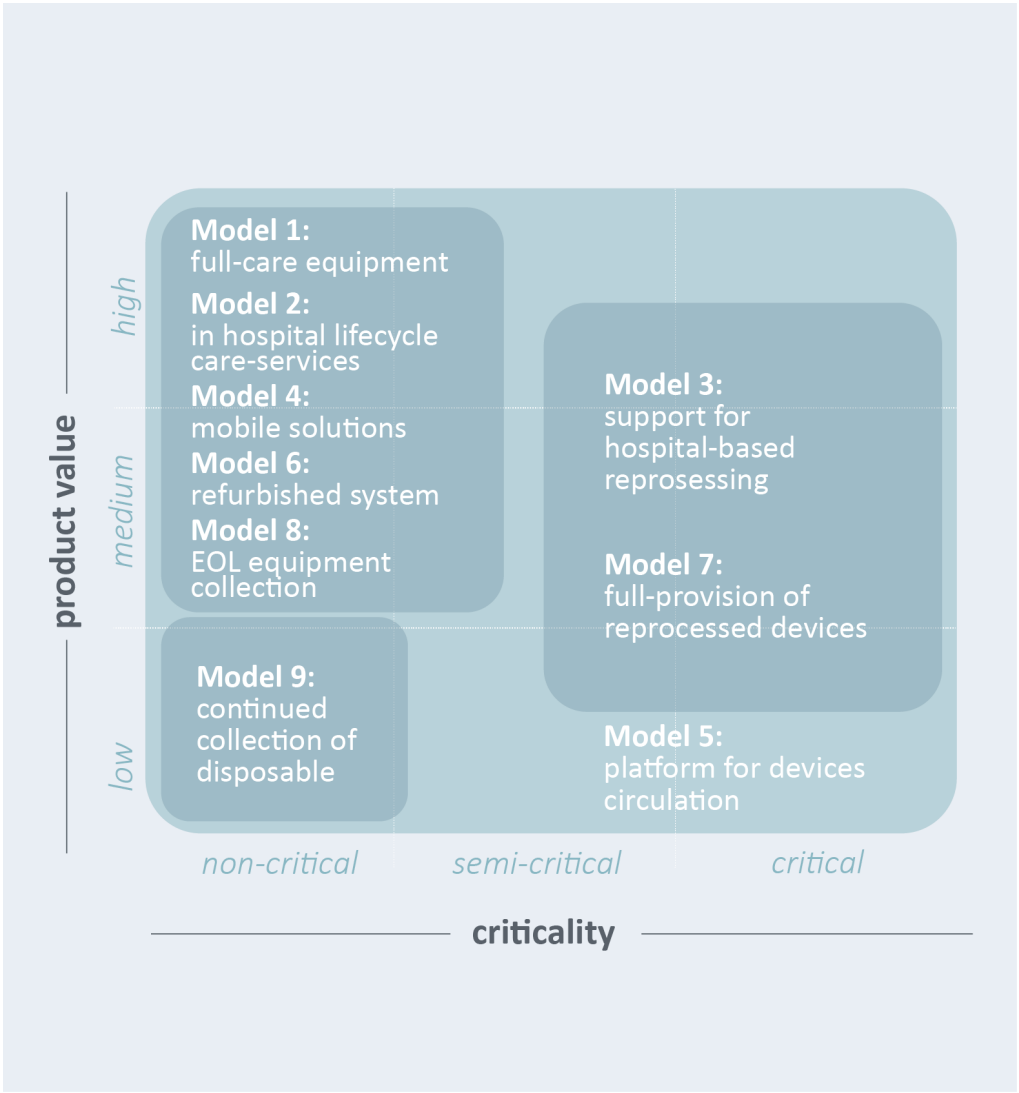


Figure 4.5: *Nine circular business models for the medical device industry. Adapted from Guzzo et al., 2020*

4.3
Including sustainability in business strategies

4.3.1 Sustainability in business strategy

Corporate Social Responsibility (CSR) has been used to frame companies' sustainability work – often times based on the idea of environmental, social, and economic sustainability as something "outside" the organisation. Companies' sustainability efforts thus become more a way to respond to external pressure – but with limited strategic importance and bearing on the core business.

To be successful, it is essential that sustainability be recognised a role in an organisation's governance just as self-evident as its economic management. A strategic approach, with goals and action plans linked to the core business, gives a boost to the work. It is crucial for sustainability work to create value for the company and be closely linked to business strategy.

Integrating sustainability into business strategy means working with **strategic sustainability.** This increased priority in companies takes into account that to achieve success, one needs to look at the entire value chain, work with materiality analysis and stakeholders in a broader sense – to focus sustainability work in order to promote both business success and sustainable development.

Status analysis

Sustainability work often starts with **a review of a company's impact.** This analysis of the status/current situation results in a number of sustainability aspects, some of which have a significant external impact. These substantial issues and aspects need to be governed somehow, i.e., there need to be routines or instructions in place on how to manage them. With the effects of climate change and social issues having a direct and indirect impact on businesses, risk analysis has started to include such external aspects – and formulate mitigation strategies to manage such risks.

The business case for sustainability

In these times of climate change - when governments, customers, and international markets are demanding sustainable solutions and sustainable business models – **there is a business case for identifying which social and environmental issues are relevant to business.** For example, strategic sustainability work can help companies succeed in the following areas:

- Regulatory requirements & directives
- Social or green criteria in public procurement
- Marketing & brand equity
- Purpose & motivation among staff
- Attracting talent
- Increased investor interest
- Customer & stakeholder demand

Alone or in combination, these can help companies seize business opportunities and gain a competitive advantage, thus generating revenues by designing and creating new products that meet current and future needs, or by creating value through environmental performance with more energy efficient products and production, using less material or more sustainable materials.

Some key tools for sustainability work

Strategic sustainability needs to be linked to and integrated into business strategy, based on an organisation's specific context, industry, market and stakeholders. This is important in order to target strategy and activities on the relevant aspects. There is a wide range of **models and tools that can support activities,** and there are **standards and systems that can provide organisations with guidance on how to structure and manage the work.**

Risk management

Risk management involves the a**nalysis of threats and opportunities.** It may be appropriate to analyse such risks in relation to the company's sustainability aspects. Such an analysis may answer some questions such as: What areas of the business do we have good control over today? What aspects of sustainability do we lack control of, and are at risk of non-compliance or goodwill loss? Taking the risk analysis further, it is also possible to include what type of social and environmental risks the organisation poses to society and the environment.

Stakeholder management

Stakeholder management is based on the **importance of the actors affected by and related to the business.** Every company has a large number of stakeholders to engage with, and their opinions can be very important when it comes to selecting and prioritising sustainability aspects to work on. The most important stakeholders are the 'key stakeholders', i.e., those stakeholder groups that have both a high level of influence and a high level of interest in the company's success or failure. The first step in engaging with stakeholders is to identify appropriate communication channels.

Materiality analysis

A structured way of considering stakeholder opinions on the company's sustainability work is to conduct a materiality analysis. **A materiality analysis can be a questionnaire describing relevant sustainability aspects.** Stakeholders can then weigh and prioritise these aspects as more or less important to work on. The aspects that stakeholders rank as most important are selected as the focus for future sustainability work.

4.3.2 Business intelligence and change

A system perspective on changes

Any organisation, any business, is inevitably part of a broader context, an ecosystem with many layers of actors. And systems, such as the global healthcare system, are also linked to other systems. This extensive web of interdependence between systems, and between organisations within systems, can be difficult to define and map in its entirety. However, understanding that **changes and disruptions in this web have both direct and indirect effects on industries, markets, and businesses,** is important in order to adapt.

The different layers of an ecosystem per se include different levels of actors, from the national and international policy levels to sectors, to organisations, to groups and individuals. All levels are affected by the transition to more sustainable business, products and services, and the changes that this entails for them. To add to the complexity, each level reacts and responds differently to current or upcoming changes. Some organisations are well equipped to adapt, others are more challenged. Some individuals are open to and welcome change, while many others are more hesitant and even resistant.

Sustainable development – a change that needs to be managed

Environmental, social and economic issues are becoming increasingly apparent also for the private sector and businesses. For most organisations, the transition to a more sustainable healthcare system implies managing change. For example, climate change is driving changes in policy across and within sectors and industries, and markets need to adapt to changing consumer demands and behaviour. Social issues are also leading to other demands concerning fairness, equality, accessibility, rights and safety, both locally and in supply chains.

Healthcare systems are sensitive to change and disruptions, not least due to the need for patient accessibility and predictability. At the same time, all dimensions of sustainability are very much at the heart of its nature and development.

Looking at the industries related to the healthcare system, there is a wide range of stakeholder groups, each pushing for different interests. The pressure for environmentally sustainable development is growing, not least in Europe, both to tackle changes and events from the outside to manage the sector's own impact on society and the environment.

Ability to adapt to sustainable development

Adapting to change in an ever faster evolving industry and marketplace starts with **identifying changes and trends as early as possible, in order to seize opportunities and mitigate risks.** Keeping an ear to the ground helps a company to review and adapt its business strategy, before the damage is done, or before other companies seize the opportunity. It reduces the risk of stagnation and being outmanoeuvred by competitors. Changes in, and around, the system happen all the time; sustainable success depends on how well organisations anticipate and adapt to them.

Building capacity in the organisation and for companies to become or remain competitive in the market comes down to **complying with legislation, requirements, and policies. However, it is also about keeping track of demand, and adapting the products or services supplied.** In healthcare – as a system and as an industry – both demands and regulation are moving towards higher expectations in terms of sustainability and sustainable solutions.

Business intelligence

Business intelligence is crucial to understanding where the industry and market is going, based on legislative developments, societal developments, and consumer behaviour. The changes taking place in the ecosystem all the time trigger responses among the entities in the system and this creates further changes. It is a dance where companies need to follow or take the lead in order to adapt their strategic moves to the music.

Being intelligent basically means keeping an eye on what is going on around the business, with lawmakers, policy-makers, competitors, consumers, and more, to identify trends and developments that need to be managed in a strategic way. How far a company needs to look, into its own ecosystem or beyond, depends on the markets it operates in, its regulatory landscape, its reliance on public procurement, its need for investment and credit, its supply chain, and so on.

To succeed with green or sustainable innovation and product development that represents something new, a change, **companies' business intelligence needs to take into account the potential reactions of key stakeholders,** both internal and external. Business intelligence means having the ability to read the trends and anticipate future and current changes in policy, legislation, customer demand and competition.

A good first step towards business intelligence and building capacity to manage change in the ecosystem is to identify and involve key stakeholders. Key stakeholder groups are exposed to changes themselves and are adapting and developing in ways that affect related businesses.

4.3.3 Governance and implementation

Governance of organisations

The term governance is often associated with governments. However, governance takes place at both the macro and meso levels (Figure 4.6). Companies, as well as hospitals and other care facilities, belong to the meso level. As such, they are influenced and impacted by governance at the macro level. This is where international, national and/or regional and local policy-making, rules and legislation affect what companies must and can do.
The governance that manifests itself at the macro level guides those in charge of companies at the meso level. **The concept of corporate governance is familiar to businesses and focuses on owners, boards and top management.**

Governance, as explained here, should be understood more as a framework that governs people's work within the organisation. Governance of organisations includes organisational structures, roles and responsibilities, policies, values, formal and informal principles, decision-making, and the management of people and personalities.
The concept of governance can be simplified by saying that governance governs management, which in turn governs people or tasks. This is not to say that managers, or people at other levels of an organisation, cannot be part of an organisation's governance framework. On the contrary, research supports the fact that organisations that involve and engage their employees in their governance and development are more likely to sustain profits and employee satisfaction.

Governance tools

Organisational governance should be seen as consisting of both hard and soft tools, or methods. A formal governance framework can consist of **tools such as policies, rules, processes, roles and responsibilities and accountabilities.** However, governance is also manifested and carried out in the form of **organisational culture, values and principles.** Although somewhat harder to define, some argue that these softer aspects of governance are the more critical ones to fostering the right attitudes for sustainable success.

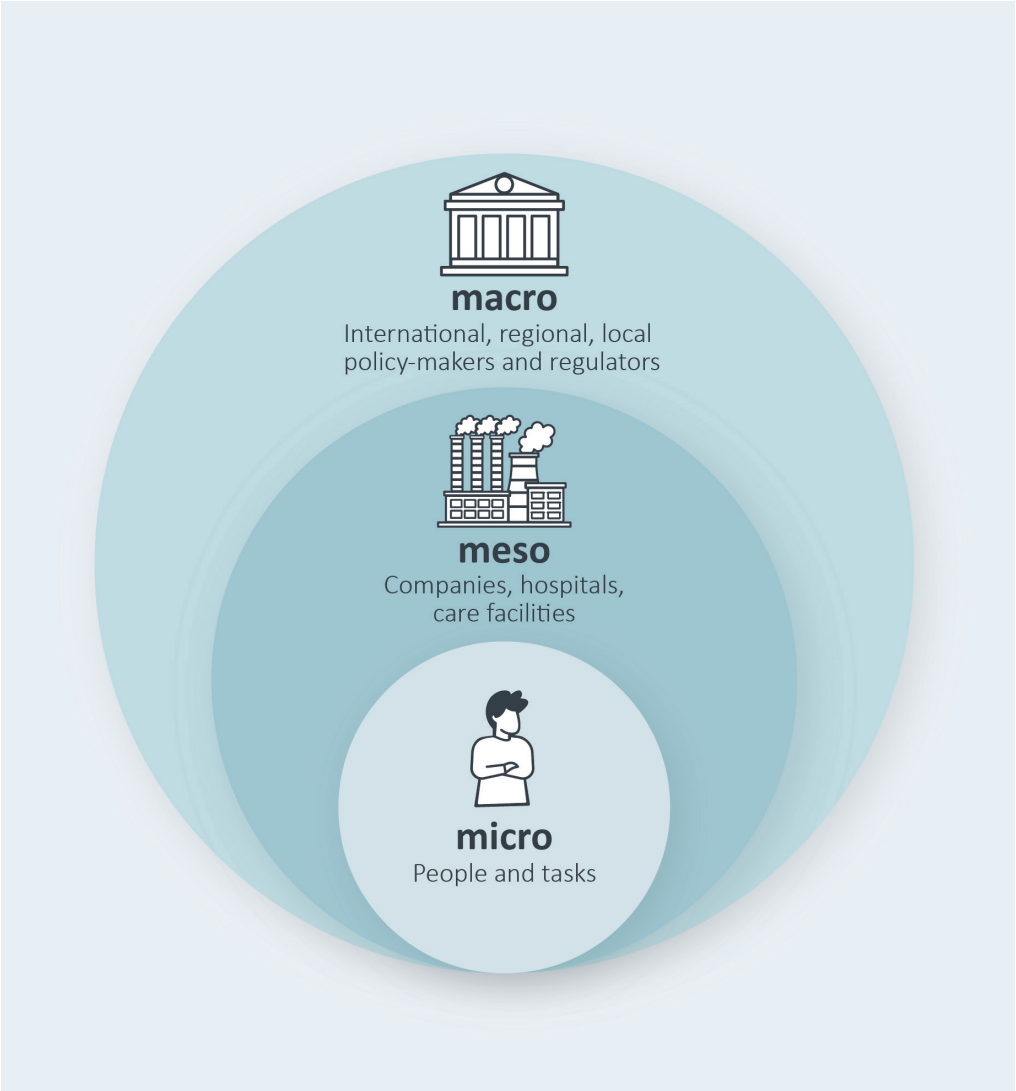


Figure 4.6: *Different levels of governance*

Governance for managing change and implementation

Understanding the governance context of customers and key stakeholders, i.e., the types of rules, regulations, policies, and mandate that govern their organisations, is important to know when developing strategy, sales, marketing and designing sustainable solutions for healthcare.

A balanced governance framework that covers both formal and informal tools allows companies to translate knowledge into behaviour, helping them to act on sustainability ambitions, goals, and requirements in their operations. Those responsible for preparing or executing the actual implementation of a company's sustainability agenda are more likely to achieve the expected effects.

Research also supports the fact that governance frameworks and management that include the operational and implementing levels of an organisation in the early stages of strategy and development are more likely to reach the desired outcomes and impacts of products or services.

Governance frameworks for social responsibility

The transition to a more sustainable healthcare system should be seen as a change that needs to be managed. **People are more likely to be open to change if the governance promotes attitudes that welcome it and transform it into an opportunity.**

Organisations and companies that want to become more socially responsible need to develop a governance framework and promote culture principles and values that support sustainable attitudes. Management needs to define goals, expectations, roles and responsibilities, and promote an organisational culture that makes sustainability and social responsibility a real priority in execution.

Management system to facilitate work

Governance is equally important in order to create the conditions for operational work. There are many practical **tools and systems that can guide and support activities, from best practice models for risk and stakeholder management to entire management systems.**

Driving sustainability requires a structured way of working. Every line of business faces a wide range of activities where sustainability may be a relevant dimension, for example in product development, supplier assessment, procurement and logistics. Having routines for such practices ensures that no crucial aspects are overlooked, and that roles and responsibilities are clearly allocated. To drive the work forward towards constant continuous improvement, objectives and goals that are aligned with business strategy need to be set.

Standards for management systems

A management system should **enable continuous improvement and act as a framework for the routines, instructions, objectives and action plans that need to be part of sustainability work.** Many companies choose to be certified according to global standards such as ISO 4001 for environmental management, ISO 9001 for quality management, ISO 13485 for MedTech equipment quality management, or ISO 45001 for occupational health and safety.
ISO 26000, a guide to social responsibility, is a standard for any organisation wishing to deepen its work and contribute to sustainable development. It is not possible to be certified according to ISO 26000, as it is a standard for guidance with no explicit requirements for compliance.
A management system comprises **recurrent monitoring and control of the status of work progress.** The concept of the PDCA (Plan, Do, Check, Act) cycle is often part of management systems.

Industry perspective on sustainability strategies in the MedTech:

Insights from the MedSilesia cluster (Poland)

Izabela Czeremcha, *Upper Silesian Accelerator for Commercial Enterprises*

The United Nations Sustainable Development Goals provide a global framework for fostering a more sustainable future. They identify priority areas for action also for the MedTech industry. Good health and well-being, responsible consumption and production, climate action and partnerships are the main goals and challenges for health and MedTech sector.
These trends are also reflected in the medtech industry among Polish medical and pharmaceutical manufacturers. According to a self-report survey of medical companies in the National Key Cluster MedSilesia, aspects of sustainability are important to small and medium-sized enterprises no less so at this point due to legal changes regarding product certification directly related to the introduced Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5 2017 on MDR (Medical Devices Regulation) medical devices, these entities have more pressing topics to tackle first. Most entities are aware of the benefits of implementing solutions aimed at sustainable development and are willing to make small changes in their businesses, especially those that require little cost, at this point these are mainly organizational or process changes. Companies are also willing to take advantage of opportunities to subsidize aspects of sustainable development, in this financial perspective these were mainly investments aimed at creating alternative sources of energy. Companies are not questioning the validity of the assumptions of sustainable development and are expanding their knowledge in this area, planning to introduce several of solutions in the further perspective of doing business.
A high level of involvement in aspects of sustainable development is observed in large companies, not infrequently pharmaceutical companies, where activities in this area are part of corporate social responsibilities (CSR) activities. These companies are aware that the activities they implement require large financial outlays, but they are also fully aware of the adequately large impact on the environment. Also, often these activities, in addition to the obvious environmental benefits, have a very large impact on the positive image of the company.
Observing the changes in EU law and the criteria for financing new ventures, we are also observing a trend that corporate sustainability aspects are becoming more common in the medtech industry. Companies are realizing that taking care of the environment and social aspects, indirectly affects our health. Such activities are also appearing for the MedTech industry in the 2023 plans, activities in line with the philosophy of sustainable development and ecological activities, such as the production of medical equipment in the spirit of zero waste and custom manufacturing according to demand, using, for example, 3D printing incremental manufacturing technology and Industry 4.0 tools.

Following the legal changes and increasing trends of medtech players' involvement in sustainability issues, start-ups that emerge in the medical sector are particularly active in following these trends, treating indications of sustainability in building their company's growth strategy as an essential part of creating a responsible business.
In the Future Health Index report commissioned by Philips (2021), which surveys the opinions of health care entrepreneurs among 14 countries, it is clear that sustainability and green energy sources identify Polish medical units as important elements in the development of Poland's health system.

Although only 2 percent of Poland's healthcare leaders currently consider implementing sustainability practices in their hospital or medical facility a priority, about half expect it to become one of their main goals in the future, more important than other needs such as improving technology infrastructure (30 percent) or facilitating the transition to remote or virtual care (27 percent). This is a significant shift, among health care leaders in Poland.

At the same time, as the Health Care Without Harm (2019) study shows, per capita carbon emissions in the health care sector in Poland are lower than in many other countries, such as the Netherlands, for example. Perhaps this explains the fact that Polish health care leaders are somewhat less likely to implement sustainable practices.

Case study

Subject	Laserobaria 2.0
Subject	Inventmed Sp. z o.o.
Year	2021
Country	Poland

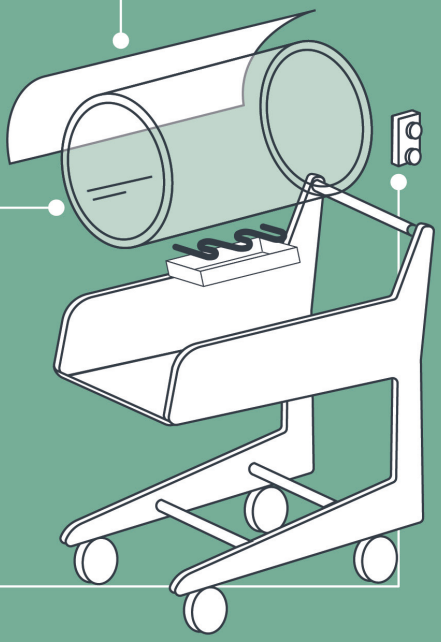
It is a multifunctional device for treating hard-to-heal wounds, edema, osteoarticular or neurological conditions. Thanks to a modular design and the use of easily recyclable materials, it minimises waste production, improves material recovery and enhance reuse, thus extending the device life cycle.

less waste produced

the use of recyclable materials, like the stainless steel of the structural components and the copper wire of the coil, allows for **easy disassembly** and the reduction of emissions of exhausted materials that can no longer be reused.

less use of resources

therapeutic chamber module elements made of acrylic panels are **easy to dismantle** and use in other manufacturing processes, **thus reducing material disposal and the use of new resources.**



less use of resources

less energy consumption

reprogrammable and reusable control components **extend the life cycle** of the device and optimise energy consumption.

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Conlusions: future perspectives in MedTech design

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The environmental and social impacts of the healthcare sector are huge and urgent and require a systemic approach that takes into account the complexity of the sector (see Chapter 1). The contribution of healthcare to climate change is even more critical than that of other sectors since it directly affects the health and well-being of the world's population, as highlighted in the annual report of the Lancet Countdown on health and climate change (Romanello et al., 2015). Today, the interconnectedness of environmental, social and economic impacts is more evident than ever: the economic losses associated with climate change impacts are increasing pressure on people and economies already challenged by the effects of the COVID-19 pandemic and the global cost-of-living and energy crises, which, in turn, further threaten the socioeconomic factors on which good health depends.

However, the nexus of the three dimensions of sustainability affects more than healthcare systems as a whole. It challenges the management and production models of individual organisations, which are called upon to respond directly or indirectly to new sustainability requirements. On the one hand, the need to respond to economic pressures calls for greater attention to energy efficiency and resource optimisation, with a positive impact on the environment. On the other hand, these needs are echoed by customers, who are increasing their demand for sustainable solutions to meet new internal priorities or policy requirements.

The MedTech industry is not left untouched by this trend: on the contrary, sustainability is a key priority at present. As Thomsen and Werner Hansen (2022) summarise, *"sustainability demands have become ubiquitous in today's MedTech industry. Regulatory requirements for sustainability are increasing. Moreover, sustainability criteria are becoming commonplace in tender processes within the healthcare sector. Also, patients want to understand the environmental impact of the MedTech products used to improve their everyday lives."* (p.12).

In the previous chapters, we have seen how the demand for a shift towards sustainability in MedTech can and must take concrete form through new products, processes and management models. Design and governance tools exist or are being developed to help the manufacturing industry meet this new challenge. However, **the demand for sustainability is a growing phenomenon that will not be limited to the issues addressed in this volume,** but will involve different issues, sectors and stakeholders along paths that are often difficult to predict. To date, studies and research hypothesise many future scenarios that address sustainability issues in different ways.

In the following pages, we will look at f**our future trends that are particularly relevant for the sustainable future of MedTech and can help define a strategic vision for the sector,** not only in the short term, but also in the medium and long term.

Climate Smart MedTech

As has been emphasised time and again on the previous pages, **the climate emergency is forcing the medical community and the healthcare sector in general to think beyond the care of individual patients to our planet's health,** on which intergenerational health and well-being depend (Sherman et al., 2021). As seen in Chapter 1.1, the health sector alone is estimated to produce 4.4% of global greenhouse gas emissions, of which 71% are mainly from the supply chain of healthcare systems through the production, transport and disposal of goods and services, food, medical devices, hospital equipment and instruments (HCWH, 2019). The 'embedded emissions' of healthcare systems are strongly determined by the design of healthcare products and services, as well as their production and distribution, which affect the entire life cycle.
Hence the **growing interest in low carbon products, packaging, and logistics, which hospitals and healthcare facilities will increasingly demand,** leveraging their organisational purchasing power. Regulatory reforms will also influence manufacturers of medical products and devices, prompting them to reduce product emissions. It is undeniable that this trend, though deemed critical, will take time. Some sustainability-leading organisations and markets are already promoting a preferential use of lower-emitting supplies. In this sense, virtuous cases show an increasing demand for medical products and devices manufactured by low-carbon suppliers who can demonstrate their sustainability through visible carbon reporting and company net-zero targets.

Although not a universally accepted term, **the notion of 'climate smart healthcare' encapsulates this growing focus on low-carbon prescribing,** which translates into different aspects, from the choice of reusable rather than single-use medical devices, to the reduction of unnecessary consumption of supplies and treatments in clinical practice, to the evaluation of the long-term impacts of a medical device. Clearly, these choices do not depend on a single stakeholder, but require collaboration between MedTech manufacturers, clinicians, patients and the complex value constellation of healthcare systems.
To this end, **MedTech design should aim to address life cycle impacts of manufactured products** while looking at optimal healthcare delivery to design sustainable care pathways. However, evaluating and improving the life cycle of a medical device does not necessarily require complex tools such as Life Cycle Assessment (LCA), which are certainly valuable but often prove to

be time-consuming, costly and ultimately a retrospective method for assessing MedTech product sustainability (Thomsen & Werner Hansen, 2022). Instead, a designer must develop his or her own combination of qualitative and quantitative methods and define a set of sustainable design principles and guidelines to evaluate and guide product design.

End-of-Life strategies from a life cycle perspective

As we have seen, current and future circular economy trends advocate a strong focus on the end-of-life of products, but from a systemic perspective. It is not just about promoting recycling and reuse but looking at the whole life cycle to create 'closed loops' in which products and materials retain their value (MacNeill et al., 2020).

To date, few studies and projects have been conducted on the adoption of end-of-life strategies in the medical device industry, despite the fact that **waste rates in the healthcare sector are alarming and on the rise** (Dahma et al. 2019). Undoubtedly, the medical sector is challenging, given the strict regulations and product risks related to the safety of patients and healthcare workers. However, it is no longer possible to overlook the environmental and economic burden of medical waste generation, which is now on the European and international policy agenda.

End-of-life strategies are manifold (King et al., 2006), ranging from device repair and upgrades to reuse and recycling. However, **future trends focus on MedTech product reprocessing, which underpins the implementation of medical device reprocessing programmes** (see Chapter 3). Indeed, this is one of the best strategies for keeping materials in use at the highest value, as the product recovers the specification of a new one, including the warranty.

For several years, the European Commission has been addressing the issue of medical device reprocessing, which is regulated in the case of explicitly reusable devices where the manufacturer must provide information on the process to allow reuse (cleaning, disinfection, and packaging), the method of sterilisation to be used, and any restriction on the number of reuses (Directive 93/42/EEC, Regulation EU 2017/745). Instead, the reprocessing of single-use medical devices is regulated by different national legislations, so that only a few countries allow it and have developed specific guidelines (e.g., Germany), while some countries prohibit it (e.g., France) and other Member States have no specific regulations (European Commission, 2010).

Circularity trends are driving a change in the medical device business model, thus promoting the sale of devices designed upstream by the manufacturer to be reused, also thanks to **new sales models based on services rather than products** (Guzzo et al., 2020). Recent market studies

confirm that the Global Medical Device Reprocessing Market is expected to reach USD 4 billion by 2028, growing at a CAGR of 13.7% over the next five years (KBV Research, 2022). In addition to the focus on environmental sustainability, this trend responds to **important economic benefits for hospitals and healthcare providers, with a view to reducing the high costs of tools and devices.** In the short term, steps need to be taken in hospital sterilisation techniques, particularly for plastics, to ensure process safety. As is the case today, **reprocessing will mainly be a third-party procedure carried out by specialised companies.** This also requires specialised professionals. We are seeing an increase in the demand for skills in the area of medical device reprocessing: short and medium-term training courses are springing up to train operators who can best manage post-use remanufacturing processes. However, it is equally crucial to train designers who are able to design upstream medical devices for remanufacturing, thus increasing the number of reusable and reprocessable devices (Hennein, Goddard and Sherman, 2022).

High-value primary health shift

If low-carbon and end-of-life strategies highlight the direct involvement of the MedTech industry and MedTech designers in particular, the following two trends are less obvious but equally fundamental.

The first is the **shift from hospital-centred care to community-based health promotion and disease prevention** (Sherman et al., 2021). This is not merely a change of place of care, which certainly improves patient well-being and quality of life, but **a real paradigm shift in healthcare services, also involving the MedTech industry.** Enabling home or community-based management of one's own health means **rethinking products for more autonomous use by patients.** This requires the empowerment of the population that the devices in use must support. In addition to criteria such as usability, safety, and the ability to control and share data, a sustainability logic should be introduced.

This is directly associated with **the concept of high-value care, whereby benefits are maximised not only in the present but also in the long term.** What is known as low-value care, in which harm or costs outweigh the benefits, is ubiquitous in healthcare systems today. It occurs when there is a mismatch - underuse or overuse - between the demand for and supply of health services and is driven not only by the structure of the healthcare system, but also by the misbehaviour of the system's actors. Overuse of healthcare services and products leads to economic damage to healthcare systems, possible supply shortages and the burden of disease resulting from the pollution generated by healthcare. In contrast, the idea of high-value care "optimises health

and wellbeing by delivery of what is needed, wanted, clinically effective, affordable, equitable, and responsible in its use of resources. High value care also maximises environmental performance, avoiding harm to public health." (Sherman et al, 2021, p.3).

This important but theoretical definition is being translated into practice through **new purchasing and procurement approaches.** According to MedTech Europe (2019), approximately 70% of all medical technologies are purchased through public procurement; therefore, an efficient procurement process is essential for all healthcare stakeholders to reduce the pressure on healthcare budgets, deliver better value to patients, make healthcare systems more sustainable and stimulate the development of high-quality medical technologies. New approaches, such as value-based procurement, go beyond volume- and price-based procurement to **evaluate MedTech solutions through a holistic approach that includes outcome-based contract award criteria.** This means that the MedTech industry is called upon to demonstrate the clear and measurable value of its technologies, services and solutions to patients, hospitals, contracting authorities, health systems, society and the environment.

Data-driven Medtech

The latest trend focuses on **the role of digital health from a socio-environmental and economic sustainability perspective.** Foresight studies conducted by Deloitte (2022) show that the MedTech industry is well positioned to drive the future of health but will need to forge new partnerships with consumer technology and digital health companies to meet changing market needs.

As mentioned above, the focus of healthcare systems is shifting from treatment to prevention and from a hospital-centred vision to home and self-care. From this perspective, the f**uture MedTech devices must combine hardware and software to enable people to diagnose and even treat medical conditions at home,** alerting healthcare teams about potential health issues before they become symptomatic.

The differentiating factor for MedTech devices will not only be the quality of the product itself, but also **the ability to collect, process and communicate the data collected through the device to improve patient well-being,** anticipate health problems, and help people change their daily behaviour. There are strong connections here with high-value care and sustainable healthcare, due to the prevention of chronic diseases and their socio-environmental impact. Moreover, the ability to influence behaviour not only generates health value, but can also engender new sustainable routines in the management of therapies, products and waste.

According to Arboleda et al. (2019), MedTech industries, which have traditionally focused on developing hardware (e.g., surgical equipment, joint replacements, diagnostic equipment, infusion pumps, pacemakers, etc.), should shift their focus to software, data collection, and advanced data analysis. While some lines of innovation will continue to be pursued by the MedTech industry alone, in other cases **new partnerships with other sectors and companies will be crucial. Specifically, consumer technology companies** will be key to driving the development of artificial intelligence, voice recognition, and AR/VR technologies. Again, the benefits are twofold: on the one hand, there is an improvement in disease prevention and management techniques through digital and robotic technologies, and on the other hand, there are new opportunities to use these technologies to improve the overall sustainability of a healthcare system. Not only on a socio-economic level, but also on an environmental level through **real-time control of devices, allowing life cycle monitoring,** with better maintenance and repair capabilities. AR/VR tools are also seen as fundamental in the training of healthcare professionals, creating true-to-life, high-performance virtual settings. Such systems, applied to real-life routines, can also be used to train and support sustainable behaviours, from waste management to resource optimisation.

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Amina Pereno is a PhD in Management, Production and Design at the Politecnico di Torino with a thesis on design for the environmental sustainability of healthcare processes and systems. She is a Researcher at the Politecnico di Torino (Department of Architecture and Design). She has also carried out research activities with the ISI Foundation (Lagrange Project) and was a visiting researcher at the Nordic Center for Sustainable Healthcare (Sweden). She is part of the research team of the Eco-Pack Observatory and co-founded Sys -Systemic Design lab. She has published articles and books for leading international journals and publishers.

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The book "Sustainability in MedTech Design. Methods, Tools and Practice" builds on this context to provide MedTech practioners with the opportunity to acquire new knowledge and skills to cope with the ongoing sustainable transition.

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