JOURNAL of MEDICAL DEVICE REGULATION

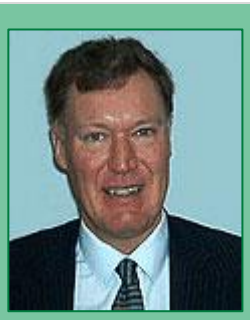
FEBRUARY 2023 SPECIAL REPRINT

Journal of Medical Device Regulation, 2023, 20(1), 61–75

Sustainability for the medical device industry – Concepts, global frameworks and EU regulatory requirements

Editorial Advisory Board

Haroon Atchia
CEO & Technical Director, Quality First International, London, UK



David Jefferys
Senior Vice President Global Regulatory, Government Relations, Public Affairs and Patient Safety, Eisai Europe Ltd, London, UK

Elena Jugo
Senior Manager, Regulatory Affairs, Codman & Shurtleff, Inc, USA (retired)

James Kuhn Jr
Regulatory Affairs Manager, ANIMAS (Johnson & Johnson Company), Chesterbrook, PA, USA (retired)

Mario Nacinovich
Senior Director, Marketing - Glaucoma, Théa Pharma US, Lexington, MA, USA

Luciano Oliveira Ferreira, RAC
Client Manager - Medical Devices, Americas, BSI, São Paulo, Brazil

Teresa Perry
Quality and Accreditation Director, LNE-GMED UK

Eliana Silva de Moraes
Senior Business Partner, Silva de Moraes & Associes, Brazil

Paul Sim
S&P Medical Devices Knowledge Manager, BSI Healthcare, UK

Val Theisz
Principal Consultant, Co-founder and non-executive Director, Certification Body Australia

Edward C Wilson Jr
Senior Counsel, Hogan Lovells US LLP, Washington DC, USA

Dr Christina Ziegenberg
Deputy Director General, BVMed, Berlin, Germany

Publisher

Published by Global Regulatory Press
Address: 1 Cooks Road, London E15 2PW, UK
Editorial Director: Victoria Clark BSc, MSc
Tel: +44 (0)1305 264797
Email: editor@globalregulatorypress.com
Website: GlobalRegulatoryPress.com

Conditions of sale

Subscriptions

- receive four issues per year (February, May, August, November) plus regular news bulletins
- supplied as a PDF by website download
- articles are fully searchable (e.g. by country/topic) in the secure subscribers' area online
- access to the full back issues library (since 2004)
- Editorial Advisory Board of international medical device experts
- exclusive special offers

A **SOLO** licence is a subscription for a single user and only the named subscriber will be able to access and read the Journal.
Order via GlobalRegulatoryPress.com.

A **STANDARD** licence is for small teams of up to 10 users located at a single site.
Order via GlobalRegulatoryPress.com.

An **ENTERPRISE** licence is for medium sized teams of up to 20 users located at a single site.
Order via GlobalRegulatoryPress.com.

A **GLOBAL** licence is for larger teams or for users in various locations.
Email us for a bespoke quote.

Academic discounts are available. Please contact us for more information.

Advertising

- **Journal**: the reference source for global medical device and IVD regulatory professionals
- **Online**: at GlobalRegulatoryPress.com
- **Email**: with highly targeted recipients in the medical device and IVD industries

To place an order or ask a question, please contact Marija Capek, Medical Device Advertising & Sales Manager at marija@globalregulatorypress.com.

Sustainability for the medical device industry – Concepts, global frameworks and EU regulatory requirements

Introduction

Sustainability is not a new concept. For some time, medical technology companies have been working on several sustainability related issues (e.g. packaging waste, affordability), yet new systemic perspectives and challenges are emerging.

Medical technology companies, like all companies worldwide, must manage numerous issues affecting their business, which can be categorised into political, economic, social, technological, environmental and legal issues. More attention is now being paid to these issues by legislators, the media and the public, but environmental issues, social issues and obviously economic viability of companies have been on executives' radar for a long time. From a systems perspective, however, issues once considered separately are now acknowledged to be interconnected. Thus, they require a holistic approach to avoid trade-offs if treated in isolated ways.

This article discusses the concepts of sustainability, and environmental, social and governance (ESG) standards, as well as the main international frameworks and policies that have emerged so that stakeholders can work towards a more sustainable world. It also looks at European Union (EU) specific sustainability related regulatory requirements and standards impacting medical technology companies, and how to successfully manage them. Finally, it examines the need for companies to adopt new governance and collaborative approaches, both internally and externally, to navigate the rapidly evolving landscape successfully.

Sustainable development, ESG standards and international frameworks

Sustainable development and ESG standards

The concept of sustainable development appeared in 1987 in the United Nation's *Report of the World Commission on Environment and Development: Our Common Future*[1], known as the Brundtland report:

> 'Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs'.

Even back in 1987 it was reported that '[u]ntil recently, the planet was a large world in which human activities and their effects were neatly compartmentalized within nations, within sectors (energy, agriculture, trade), and within broad areas of concern (environment, economics, social). These compartments have begun to dissolve'. The environment, economy and social dimensions have now become the so-called three pillars of sustainability.

In 2004, the report *Who Cares Wins – Connecting Financial Markets to a Changing World*[2], which was published under the auspices of the United Nations Global Compact Program and supported by financial institutions, provided 'guidelines and recommendations on how to better integrate environmental, social and corporate governance issues [ESG issues] in asset management, securities brokerage services and associated research functions'.

Millennium Development Goals and Sustainable Development Goals

In 2000, the *United Nations Millennium Declaration* was signed, with world leaders committing to combat poverty, hunger, disease, illiteracy, environmental degradation, and discrimination against women. Eight Millennium Development Goals (MDGs)[3] were derived from this Declaration. These eight MDGs have now been superseded by 17 Sustainable Development Goals (SDGs)[4], adopted by all United Nations Member States in 2015 through the *2030 Agenda for Sustainable Development*[5]. Stakeholder consultations and collaborations are becoming common practices to advance sustainability goals, as one actor cannot deliver alone.

Global sustainability and ESG issues relevant to the medical technology sector

The *Medical Equipment & Supplies Sustainability Accounting Standard* (version 2018-10)[6] lists the following most significant issues for medical technology companies: affordability and pricing; product safety; ethical marketing; product design and lifecycle management; supply chain management; and business ethics.

While not all medical technology companies have considered these issues as business opportunities, they may be worth considering. For example, healthcare and biological wastes amount to 1.22 million metric tonnes in the EU in 2020[7] and the eHealth devices market is planned to continue growing (from US$12.2 billion in 2021 to US$18.77 billion in 2027)[8]. Reprocessing and reuse of single-use products have been demonstrated as significant opportunities for both environmental and financial benefits for public health systems. In 2018, reprocessing companies in the USA, Canada, and Europe reduced hospital solid waste generation by almost 7,100 tons and generated cost savings of more than US$470 million for device consumers[9].

An evaluation[10] by Health Care Without Harm revealed that the global health sector, as a country, would be the world's fifth biggest emitter of greenhouse gases, with 4.4% of the total global emissions. 70% of those emissions relate to the value chain and supply chain of products, making environmental performance of supply chain management a central opportunity (with greenhouse gas emissions as one of the critical dimensions).

Lifecycle analysis also provides examples of how the reuse of a device has the potential to significantly reduce the environmental footprint for each additional device usage. Results of a study by Schulte, Maga and Thonemann[11] show that using a remanufactured medical catheter has a significantly lower impact on global warming (0.87 kg CO_2-eq./catheter) than using a catheter from the virgin production route (1.75 kg CO_2-eq./catheter).

Sustainability-related policies in various regions

As countries have adopted the SDGs, they have adopted policies, legislation and administrative measures to support the implementation of these SDGs.

In the EU, the European Commission proposed a European Green Deal[12] in December 2019 as one of its six priorities for 2019–2024. Its aim, which encompasses the environmental, economic and social dimensions of sustainability, is to 'transform the EU into a modern, resource-efficient and competitive economy, ensuring:

- no net emissions of greenhouse gases by 2050 [with an intermediate target of emissions reduction by at least 55% by 2030, compared to 1990 levels]
- economic growth decoupled from resource use
- no person and no place left behind'.

In other world regions, countries have also adopted plans to implement the SDGs, which are influencing the development of their legislative framework. Some examples of plans and organisations are:

- Japan's SDGs Promotion Headquarters[13]
- USA's Federal Sustainability Plan[14]
- China's cooperation with the United Nations System via the United Nations Sustainable Development Cooperation Framework for the People's Republic of China 2021–2025[15] and China's five-year plan for economic and social development[16]

- UK's Environment Act 2021[17] and its 'Greener National Health Service (NHS)'[18] plan, where NHS England must reach net zero greenhouse gas emissions by 2045. One of its pillars is to encourage innovative approaches, specifically mentioning a switch from disposable to reusable medical equipment and use of technologies to avoid plastics.

In 2020, about 74% of senior managers in global medical device companies cited the changing regulatory environment as a challenge[19]. The coming years will see many regulatory changes focusing on sustainability.

Focus on the EU: The Green Deal and its implementation policies and strategies

As a holistic approach, the European Green Deal has led to several policies and strategies for different domains such as industry, environment and oceans, climate, research and innovation. It is not always easy to navigate them as the policies/strategies/actions refer to each other, yet for the medical technology industry, the following strategies/policies are the most relevant ones:

- Circular Economy Action Plan[20] (CEAP), which aims to make sustainable products the norm in the EU, among other aims;
- Chemicals Strategy for Sustainability[21], which aims to better protect citizens and the environment, and boost innovation for safe and sustainable chemicals;
- Zero Pollution Action Plan[22] with a zero pollution vision for 2050 and targets for 2030;
- European Industrial Strategy[23], which supports the twin transition to a green and digital economy, making EU industry more competitive globally, and enhancing Europe's open strategic autonomy.

The EU regulatory instruments (Regulations and Directives) and their requirements, together with relevant standards to support the implementation of the Green Deal goals, are presented in the next section. While Regulations apply directly in the EU, it is important to highlight that Directives must be transposed into the national legislation of each EU Member State, so they take more time to have concrete effects, with possible country-specific and potentially more stringent requirements than the Directive text.

EU sustainability-related regulatory requirements and standards

Although several existing EU regulatory instruments with a 'sustainability component' have already been implemented, these instruments have been revised or are under revision to make a consistent set of requirements with the Green Deal objectives and with newly adopted legislation.

The following existing regulatory instruments and their requirements will not be further detailed in this article (a short sentence of the most recent developments is added as an insight):

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). The Joint Research Centre's *Safe and Sustainable by Design chemicals and materials – Review of safety and sustainability dimensions, aspects, methods, indicators, and tools*[24] supports the medical technology industry's ecodesign phase.
- Directive 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
- Directive 2012/19/EU of 4 July 2012 on waste electrical and electronic equipment.
- Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and its related Best Available Techniques reference documents.
- Apart from Directive (EU) 2022/2464[25] on corporate sustainability reporting (the Corporate Sustainability Reporting Directive, CSRD) discussed below, other key EU sustainable finance regulations that may affect financing of medical technology companies include Regulation (EU) 2019/2088 of 27 November 2019 on sustainability-related disclosures in the financial services sector (effective 10 March 2021) and Regulation (EU) 2020/852 of 18 June 2020 on the establishment of a framework to facilitate sustainable investment (fully effective 1 January 2023).

From strategy to reporting – requirements for a 'plan-do-check-act' approach

1. Plan: Strategy development

Identification and management of sustainability issues are fundamental pieces of corporate strategy design. The recently published CSRD[25], amending the Non-Financial Reporting Directive (2014/95/EU), requires sustainability reporting standards to 'promote a more integrated view of all the information published by undertakings in the management report to provide users of that information with a better understanding of the development, performance, position and impact of the undertaking'.

Information financial materiality is also defined, under the draft CSRD-related European Sustainability Reporting Standard *ESRS 1 – General Principles*[26]:

> 'Materiality is to be understood as the criterion for the inclusion of specific information in sustainability reports. It reflects (i) the significance of the information in relation to the phenomenon it purports to depict or explain, as well as (ii) its capacity to meet the needs of the stakeholders of the undertaking, allowing for proper decision-making, and more generally

(iii) the needs for transparency corresponding to the European public good. The implementation of materiality implies the use of thresholds and/or criteria'.

The information necessary to understand both 'inside-out' and 'outside-in' perspectives – respectively, the undertaking's impacts on sustainability domains (e.g. environmental impacts) and the information necessary to understand how sustainability matters (e.g. climate change related impacts) affect an undertaking and its business model – will be required. This is so-called 'double materiality' reporting.

Article 19a of the CSRD states that the following information, among others, 'shall be clearly identifiable within the management report, through a dedicated section of the management report':

- brief description of the undertaking's business model and strategy;
- a description of the time-bound targets relating to sustainability matters set by the undertaking, including, where appropriate, absolute greenhouse gas emission reduction targets at least for 2030 and 2050;
- a description of the role of the administrative, management and supervisory bodies with regard to sustainability matters [governance aspects];
- a description of the undertaking's policies in relation to sustainability matters;
- information about the existence of incentive schemes linked to sustainability matters which are offered to members of the administrative, management and supervisory bodies.

All sizes of enterprises, as well as companies with a registered place of business outside the EU, are in scope of the CSRD. Companies are expected to implement these regulatory amendments, with staged deadlines, by 2026. Financial-type assurance (audit) will be required on the reported information, making a change on the currently voluntary sustainability reports published by companies that may not always undergo such assurance processes.

European Sustainability Reporting Standards (ESRSs), providing guidance on identification of material ESG issues and information to be reported under the CSRD, are planned to be adopted by the Commission by 30 June 2023. The draft standards[27] are as follows:

- Two cross-cutting standards: ESRS 1 – General requirements and ESRS 2 – General disclosures.
- Five environmental topics standards: ESRS E1 – Climate change, ESRS E2 – Pollution, ESRS E3 – Water and marine resources, ESRS E4 – Biodiversity and ecosystems and ESRS E5 – Resource use and circular economy.

- Four social topics standards: ESRS S1 – Own workforce, ESRS S2 – Workers in the value chain, ESRS S3 – Affected communities and ESRS S4 – Consumers and end-users.
- One governance topic standard: ESRS G1 – Business conduct.
- Six appendices.

2. Do: Research and development, procurement and operations

Research and development

In the research and development phase, as a regulatory instrument that supports the CEAP, a new proposal for a Regulation[28] establishing a framework for setting ecodesign requirements for sustainable products specifies requirements for the design of a medical device and its use including repair, disposal and recycling. Medical devices were not in the scope of the current Ecodesign Directive 2009/125/EC but will fall into scope of the upcoming Ecodesign Regulation. The proposed Regulation requires that the Commission prepares additional delegated acts to specify the ecodesign requirements for certain product types and clarify the regulatory pathways, in case industry-led measures are not adopted as 'self-regulation measures' (Article 18). The current draft outlines new requirements in the areas of (Article 5):

- durability;
- reliability;
- reusability;
- upgradability;
- reparability;
- possibility of maintenance and refurbishment;
- presence of substances of concern;
- energy use or energy efficiency;
- resource use or resource efficiency;
- recycled content;
- possibility of remanufacturing and recycling;
- possibility of recovery of materials;
- environmental impacts, including carbon and environmental footprint;
- expected generation of waste materials.

The final requirements for conformity assessment must be specified by delegated acts. Either way, the proposed Regulation requires a set of technical documentation to demonstrate compliance that

is based on objective evidence following the state-of-the-art practice. Impacts on the development, manufacturing, and post-market phase of medical devices will have to be reflected by updating the implemented Quality Management System. Most obviously, the design development process will have to ensure that ecodesign requirements are addressed, with consideration of aspects relating to the entire product lifecycle.

Batteries play an important role in many medical devices. With the proposal for a Regulation concerning batteries and waste batteries[29], the Commission aims to promote a circular supply chain for batteries, with obligations that will indirectly impact medical technology companies, including:

- supply chain due diligence;
- a maximum carbon footprint threshold;
- recycling efficiency levels;
- performance, replaceability, reporting, and labelling requirements;
- extended producer responsibility (EPR) for collection and recycling of used batteries;
- and a digital battery 'passport' to capture key lifetime events.

Processes such as service, maintenance, and repair may have to be adapted or developed to comply with new requirements. Regulation (EU) 2017/745 on medical devices (MDR) primarily regulates the market access of medical devices in the EU. Emerging requirements from other regulations, such as the future Ecodesign Regulation, must be considered by manufacturers as well and thus demand an integrated implementation approach to gain market access. Both Regulations require a set of technical documentation to demonstrate conformity with the different design and usage related requirements. While the MDR focusses on safety and performance characteristics, the Ecodesign Regulation targets sustainability related design attributes. The means of verification and validation for both Regulations is identical, with objective evidence in the form of scientific data that takes into account harmonised standards. Any device-specific requirements shall be consolidated as design input requirements under the design development process of the manufacturer's Quality Management System and undergo the subsequent phases of the development process generating the required verification or validation evidence. An exhaustive list of design input requirements is needed to make sure that the end product meets the requirements of both Regulations. This approach would allow manufacturers to demonstrate conformity for both Regulations with one set of technical documentation and one design traceability matrix rather than managing different sets of files. It would reduce process complexity as well as efforts in the creation and maintenance of technical documentation. New labelling information on ecodesign requirements must be created as defined under Article 7 of the Ecodesign Regulation.

Any claims on sustainability must be based on objective evidence, a similar requirement as for medical claims. An 'ecodesign evaluation' (similar to a clinical evaluation) that identifies, discusses, and evaluates any aspect of a product in regard to its contribution to more sustainability, compliance with ecodesign requirements as well sustainability claims, might be necessary to avoid the abuse of misleading claims.

Procurement

The proposed Directive on corporate sustainability due diligence[30] extends manufacturers' responsibilities over the supply chain of its products. Manufacturers would be required to implement sustainability-related criteria into their supplier management process. The interdependency of processes in terms of new sustainability reporting requirements means that any data and information needed for the calculation of a product's environmental footprint (PEF) or organisation environmental footprint (OEF) and reporting under the CSRD will have to be included in the purchasing specifications or supplier quality agreement. The footprint of the purchased article could logically become a criterion of the purchasing decision between multiple potential suppliers.

Supplier audits would have to evaluate sustainability-related performance, such as environment, health and safety issues, labour issues, secure workplaces, or governance aspects.

The economic dimension (minimum costs) may conflict with environmental and social dimensions (high level of protection). The International Organization for Standardization (ISO) 20400 standard on sustainable procurement[31] provides companies with guidance on how to integrate sustainability into an organisation's procurement process. It also covers political and strategic aspects to align procurement with the company's sustainability goals and objectives.

In the social and governance dimensions, the Organisation for Economic Co-operation and Development has published a guidance document to support companies in their progress to make supply chains more sustainable[32]. Besides enhancing better work conditions and more secure workplaces, sustainable procurement is expected to create more robust supply chains, as the due diligence assessment covers social, environmental, and geopolitical risk scenarios.

Operations

ISO 14001 is a recognised standard on environmental management systems which aims to improve a company's environmental performance[33]. Based on new ecodesign work during the research and development step and decisions in procurement, operations may need to change to include new product features or even end-of-life circular strategies such as repair or recycle. All departments concerned in operations must work in collaboration to implement the changes in a productive way.

During operations, measurement of ESG key performance indicators (KPIs) will be required on the relevant items, such as (non-exhaustive list):

- **Environment**: energy, water and material consumptions; waste quantities.
- **Social**: recruitment diversity; human resources management, including health and safety performance.

3. Check: Performance assessment, reporting / Act: trigger adjustments and inform new strategy

According to the CSRD, a performance assessment against set targets using KPI measurements must be reported. Due to the financial nature of the reported material information, companies may want to revisit which department holds the responsibility for sustainability reporting, moving from the quality/environment health and safety, marketing or legal department to the financial department, with its accounting-related methods, as assurance will be required. All departments will have to be involved for an efficient management of the ESG issues. Apart from the reporting, the information and results from the performance assessment must be evaluated against the short-term and long-term company targets (e.g. 50% reduction in greenhouse emissions by 2030, net zero by 2050) to validate that the implemented measures are capable of reaching the defined goals. If required, companies must adjust the implemented measures to ensure sustainability targets will be met.

Sustainability must be understood and approached as a systematic matter that requires regular review, evaluation (including reporting), and adjustment actions.

Critical environmental sustainability issue perspective

Considering the requirements from the proposed Ecodesign Regulation and environmental impacts relating to the medical technology industry, major improvements must be achieved on the following material issues:

- single use;
- waste/packaging;
- energy consumption and related greenhouse gas emissions.

Single use versus reuse of medical devices

The EU MDR regulates the reprocessing of single-use devices in Article 17. The success of reprocessing companies demonstrates the technical and economic feasibility of ensuring device safety and sustainability at the same time when reprocessing single-use devices for reuse. If this can be achieved

by third-party companies, this is an option for the original manufacturer too. The actual decision of whether manufacturers change from single use to reuse of devices might be linked primarily to the business strategy rather than to its technological feasibility. Customers under financial pressure, as well as public health systems, are supposed to highly appreciate more economic medical devices and medical interventions, which creates a business opportunity for manufacturers of single-use devices. For the development of safe and effective devices, the later reuse and reprocessing must be reflected under the design input requirements in terms of, for example, material resistance to temperatures and chemicals used during reprocessing as well as cleanability of critical design parameters and geometries such as small lumens. For the validation of reprocessing instructions, ISO 17664:2017, *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices*[34], reflects the current state-of-the-art for meeting the MDR requirements.

Waste/packaging

Annex I to the EU MDR requires medical devices to be appropriately protected during distribution to ensure safe and effective use. Therefore, manufacturers put significant effort and resources into the development of safe packaging concepts to maintain and protect a device's integrity. The downside of this safety requirement is a high demand for packaging material and the generation of excessive waste. The World Health Organization states that one-third of healthcare services worldwide fail to properly dispose of waste[35]. The ISO technical committee ISO/TC 122 is working on the ISO 18600 series[36] with the intent to support manufacturers with issues ranging from reuse and recycling to environmentally conscious packaging design.

As part of the Waste Framework Directive (Directive 2008/98/EC), the European Commission has introduced the waste hierarchy as the foundation of a circular economy[37]. The concept follows the approach of prevent, reduce, reuse, recycle, and eventually recover any material or component, leading to a minimum quantity of waste disposed.

Country, community and city level administrations jointly manage the infrastructure for public waste management and recycling processes. Manufacturers are responsible for reducing the amount of packaging material and making the packaging design as sustainable as possible. Both public and private stakeholders need to take action to reach the goal of the European Green Deal of implementing a circular economy by 2050. A recently proposed revision of the EU legislation on packaging and packaging waste[38] will bring new requirements.

The International Electrotechnical Commission (IEC) standard 63120[39] on refurbishment of medical electrical equipment, medical electrical systems and sub-assemblies and reuse of components

as part of the extended lifecycle, currently under development, will provide an industry-specific framework.

The roadmap of the European Commission to a circular economy is supported by ISO and its technical committee TC 323. This technical committee is working on the ISO 59000 series[40] to provide standardisation in the field of a circular economy by developing frameworks and guidance for the implementation of activities to maximise the contribution towards sustainable development.

The business model 'servitisation' (or 'product-as-a-service', 'anything-as-a-service'), which essentially means 'use it instead of own it', is becoming more and more popular with companies formerly acting as classic device manufacturers. Instead of buying a device, customers 'pay per use (or service)' while the manufacturer remains the owner of the product throughout its entire lifecycle. Servitisation can offer competitive advantages as it does not require high upfront payments for clients, improves the customer relationship and allows for more customised solutions. It leads to increased customer satisfaction, especially in the context of digitalisation and data analysis, while at the same time helping to increase the rate of recycled and recovered device components and materials. Overall, the service sector makes up a growing proportion of the world's gross domestic product with high margins[41].

Energy consumption and related greenhouse gas emissions

One of the European Green Deal's main goals is to be carbon net zero by 2050. This means that the EU would not emit more greenhouse gases than it captures (via natural or engineered sinks). To achieve this goal, a transition from fossil-based energy to clean and renewable energy, both for the manufacture and for the use of the devices, is a crucial aspect.

As the global health sector significantly contributes to the greenhouse global gas emissions (with the production lifecycle stage usually having the greatest impact), a transition to clean energy for the production of medical devices is a way to address multiple requirements. Indeed, the Ecodesign Regulation and the CSRD will require improvements and the reporting on the carbon footprint of medical devices.

Currently, no common approach for the assessment of the lifecycle environmental impact exists that is accepted throughout the EU, with national schemes in place that must be followed. The ISO 14060 series[42] provides guidance for the implementation of project- and programme-based greenhouse gas management of organisations while ISO 14040[43] and 14044[44] set out the principles, framework, requirements, and guidelines for lifecycle assessments of products and services.

The Ecodesign Regulation will require the carbon footprint of a device to be compared with the footprint(s) of similar devices available on the market as benchmarking. As carbon footprint

assessments reflect the entire value chain of a product, it covers the impact of involved raw materials, potential extraction activities, and supply chain activities. Further down the value chain, manufacturing effects and emissions from the final distribution are added. The PEF is also an option for calculating the energy consumption over the lifecycle, and benchmarking against similar products. The PEF is part of the CEAP, as a way for companies to substantiate their environmental claims[45].

Conclusions

Overall, the most important requirement for medical device manufacturers remains to provide safe and effective devices that are compliant with the general safety and performance requirements of the EU MDR. As safety and performance in the context of the MDR refer to patient treatment, the aspect of safety from an environmental, health and safety, and more global sustainability perspective is not specifically mentioned. Still, manufacturers applying the harmonised standard ISO 14971:2019, *Medical devices – Application of risk management to medical devices*[46], have to include, analyse and assess risks to the environment already.

The European Commission has proposed new Regulations and Directives to address the aspect of 'planet health', which is inseparable from human health. Through the CSRD requirements, companies will have to review their strategy and consider their ESG-related material issues so they can improve their overall sustainability performance, in a constantly changing environment.

The proposed Ecodesign Regulation aims at more sustainable device design and usage, focusing on reuse, durability, and recycling as well as the reduction of waste. The Regulation makes lifecycle assessments for products mandatory to achieve transparency of the actual environmental footprint as a new factor for investment or purchasing decisions. The main challenge for manufacturers is likely to be the holistic integration of sustainability aspects and requirements into the company's (quality) management system, with clearly defined interfaces between the involved departments. Indeed, the affected processes cover the entire product lifecycle beginning with the appropriate design input requirements and ending with the recycling or disposal requirements. The EU MDR is forcing manufacturers to update processes and technical documentation and the upcoming Regulations and Directives will bring a new wave of changes. It will necessitate a holistic understanding of the requirements to allow a smooth and effective integration into strategy, processes and product designs.

As always, challenges come along with new opportunities. By reviewing existing business models, market demands and the upcoming sustainability requirements, the foundation for future competitiveness of companies will be set in the changing economic, regulatory, social and natural environment. As Albert Einstein allegedly said, we cannot solve a problem with the same thinking we

used when we created it. Established business models will become obsolete and replaced with sustainable solutions that reflect the demand from all involved stakeholders such as regulators, customers, healthcare systems, investors, and the environment.

References

1. https://sustainabledevelopment.un.org/content/documents/5987our-common-future.pdf
2. https://www.unepfi.org/fileadmin/events/2004/stocks/who_cares_wins_global_compact_2004.pdf
3. https://www.un.org/millenniumgoals/
4. https://sdgs.un.org/goals
5. https://sdgs.un.org/2030agenda
6. https://www.sasb.org/standards/download/?lang=en-us
7. https://www.statista.com/statistics/781149/hazardous-waste-generation-european-union-eu/
8. https://www.statista.com/outlook/dmo/digital-health/ehealth/ehealth-devices/worldwide
9. https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01118
10. https://noharm-global.org/documents/health-care-climate-footprint-report
11. https://www.mdpi.com/2071-1050/13/2/898
12. https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
13. https://www.mofa.go.jp/policy/oda/sdgs/effort/index.html
14. https://www.sustainability.gov/pdfs/federal-sustainability-plan.pdf
15. https://china.un.org/en/sdgs
16. https://en.ndrc.gov.cn/policies/202203/P020220315511326748336.pdf
17. https://www.legislation.gov.uk/ukpga/2021/30/contents/enacted
18. https://www.england.nhs.uk/greenernhs/national-ambition/
19. https://www.statista.com/statistics/938852/challenges-for-medical-device-company-managers-global/
20. https://environment.ec.europa.eu/strategy/circular-economy-action-plan_en
21. https://environment.ec.europa.eu/strategy/chemicals-strategy_en
22. https://environment.ec.europa.eu/strategy/zero-pollution-action-plan_en
23. https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy_en
24. https://publications.jrc.ec.europa.eu/repository/handle/JRC127109
25. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L2464
26. https://www.efrag.org/Assets/Download?assetUrl=%2Fsites%2Fwebpublishing%2FSiteAssets%2FED_ESRS_1.pdf
27. https://www.efrag.org/lab6
28. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0142
29. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0798
30. https://commission.europa.eu/business-economy-euro/doing-business-eu/corporate-sustainability-due-diligence_en
31. https://www.iso.org/standard/63026.html
32. https://www.oecd.org/investment/due-diligence-guidance-for-responsible-business-conduct.htm
33. https://www.iso.org/standard/60857.html
34. https://www.iso.org/standard/62952.html
35. https://www.who.int/publications/i/item/9789240039612
36. https://www.iso.org/committee/52082/x/catalogue/
37. https://environment.ec.europa.eu/topics/waste-and-recycling/waste-framework-directive_en
38. https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7155
39. https://www.iec.ch/dyn/www/f?p=103:38:0::::FSP_ORG_ID,FSP_APEX_PAGE,FSP_PROJECT_ID:1359,23,100214
40. https://www.iso.org/ics/03.100.01/x/
41. https://www2.deloitte.com/us/en/insights/economy/issues-by-the-numbers/trade-in-services-economy-growth.html

42. https://www.iso.org/ics/13.020.40/x/
43. https://www.iso.org/standard/37456.html
44. https://www.iso.org/standard/38498.html
45. https://ec.europa.eu/environment/eussd/smgp/initiative_on_green_claims.html
46. https://www.iso.org/standard/72704.html

Alain Renard is a sustainability expert with 20 years of experience in various industry sectors. His areas of expertise are the EU REACH and CLP Regulations, waste and waste transport legislations and ESG strategy development. He is managing NSF's National Centre for Sustainability Standards (NCSS), where he works with various stakeholders to identify standardisation needs, embedding sustainability dimensions in existing standards and how to advance sustainability impacts.

Robert Speer is a graduated biomedical engineer with 15 years of experience in the medical device industry. He is a consultant at NSF Health Sciences based in Hamburg, Germany. He consults medical device manufacturers on regulatory affairs and quality management with particular focus on enabling market access strategies for the European Economic Area.