# Life Cycle Compliance Management in Healthcare Industry Complex Devices

Tiziano Miroglio[a)], Sergio Paddeu[b)], Flavio Tonelli[c)]

*a) Dipartimento di Ingegneria Meccanica, Energetica e Gestionale, University of Genova, Via All'Opera Pia 15, 16145 – Genova – Italy (tiziano.miroglio@edu.unige.it)*

*b) Esaote S.p.A., Via Enrico Melen 77, 16152 – Genova – Italy (sergio.paddeu@esaote.com)*

*c) Dipartimento di Ingegneria Meccanica, Energetica e Gestionale, University of Genova, Via All'Opera Pia 15, 16145 – Genova – Italy (flavio.tonelli@unige.it)*

**Abstract**: This article delves into the multifaceted challenges associated with achieving sustainability in the complex medical devices industry. It emphasizes the importance of EU policies and regulations in addressing these challenges, particularly in relation to hazardous substances and critical raw material in their usage as governed by EU regulations. The supply chain of medical devices is identified as a key area requiring sustainable solutions, particularly in terms of raw materials sourcing and the management of critical raw materials. The adoption of sustainability principles and circular economy concepts is crucial for minimizing waste generation and reducing the industry's environmental footprint. To conduct this study, it has been employed the Delphi method, and different experts have been interviewed. With the collected data a conceptual map containing the main topics has been represented. The attended output is to provide a visual representation that highlights the interconnectedness of these challenges, fostering a collaborative approach and encouraging the adoption of sustainable practices.

**Keywords**: Industrial Sustainability, Medical Devices, Life Cycle Compliance, Delphi Method, Conceptual Map.

## I. INTRODUCTION

Sustainability has become a priority for environmental protection, and for the future development, considering the limited resources and the constant increase of human needs[1]. Sustainability, however, is a broader concept, since it encompasses various dimensions and considerations that aim to address the long-term well-being of society, the economy, and the environment[2]. Nowadays this concept is applied to all industry fields and modern industry must face this topic, because the environmental burden is growing more and more. To this end Industrial Sustainability focuses onto industrial activities. Whitin this domain, the term *sustainable manufacturing* is often used to describe the characterization and reduction of the environmental impacts of manufacturing practices[3]. Hence, European Union is trying to solve this difficult problem through laws and policies that could ensure a lower environmental impact for the manufacturing sector. These regulations cover various aspects of environmental management, including sustainable resource use, waste management, pollution control, and the reduction of greenhouse gas emissions. These circumstances oblige industries to simultaneously cope with the pressure of environmental regulations and the difficulties of a more conscious supply chain management, in addition to their daily business. In this scenario, it is not only the challenge of environmental pollution that is becoming acute but the challenge of global resource scarcity as well. The increased competition for access to scarce or critical resources has become another major concern for manufacturing industry in addition to fulfilling obligations on environmental legislation at minimum cost[4]. European countries have long recognized the importance of industrial sustainability and have implemented robust legislation to mitigate ecological harm[5]. In recent years, these regulations have increasingly targeted the medical devices industry, as it is a significant contributor to environmental pollution and scarce resource depletion[6],[7]. This industrial field has made remarkable strides in improving patient care and revolutionizing healthcare practices. However, these advancements have also brought about significant environmental challenges that demand immediate attention. As we navigate the 21st

Century, it is crucial to address the sustainability impact of medical devices and align the industry with sustainable practices. Moreover, the European laws and regulations, renowned for their stringent environmental standards, play a pivotal role in shaping the landscape of the medical devices industry. One of the pressing issues revolves around the sourcing and supply of raw materials. The development and production of medical devices rely heavily on materials as metals, plastics, ceramics, and electronics. However, the extraction and processing of these raw materials often have detrimental environmental and social consequences[8]. Furthermore, the increasing demand for medical devices, presents a significant challenge to the industry[9]. As the global population grows and healthcare becomes more accessible, securing a sustainable and reliable supply of raw materials becomes paramount. The scarcity and uneven distribution of crucial minerals and metals further exacerbate this challenge, potentially leading to disruptions in the production continuity of essential medical devices for some countries. By understanding the magnitude of these challenges and exploring viable solutions, stakeholders within the medical devices industry can work towards fostering sustainability and mitigating the adverse environmental impacts associated with device development and manufacturing practices. This article aims to provide a comprehensive overview of the sustainability issues plaguing the medical devices industry, with a particular focus on the European context. We will examine the existing laws and regulations implemented by the European Union to address environmental concerns and promote sustainable practices. Additionally, we will delve into the complexities surrounding the sourcing and supply of raw materials, exploring potential strategies and innovative solutions to ensure a steady and responsible supply chain. For this purpose, we decided to apply the Delphi method[10], a research technique which allows to gather information on complex problems through expert interview. It is a valuable tool for tapping into expert knowledge, facilitating consensus-building, and generating informed insights. It helps overcome individual biases, fosters collaboration among experts, and provides a structured approach to decision-making in complex and uncertain situations. By organising the collected data, the expected output is a *concept map*, or *conceptual map*, to represent the complexity of this topic and deriving relationships and priorities to be addressed in an industrial research agenda. The study conducted in this research targeted imaging medical devices manufactured by Esaote S.p.A. The aim was to analyse the environmental issues, European laws, and regulations, associated with these specific medical devices.

## II. Methodological Approach

### *A. Systematic Literature Review*

To provide a comprehensive analysis of the environmental issues, European laws and regulations, the sustainability knowledge in the medical devices industry, an extensive literature review was conducted. It consisted in a systematic analysis of numerous relevant articles, reports, and regulatory documents obtained from reputable scientific databases and authoritative sources. The research strategy aimed to capture a broad range of articles related to sustainability challenges, environmental impacts, European laws and regulations, and raw materials supply in the medical devices industry. Keywords and key phrases, such as *medical devices industry*, *environmental impact*, *sustainability*, *European regulations*, *raw materials*, *supply chain* were used to retrieve the most relevant literature. Following the initial search, articles were screened based on their titles and abstracts to identify the ones directly related to the aforementioned topics. The selected articles were then assessed for their relevance and credibility by reviewing the full texts. The reference lists of the identified articles were also examined to ensure the inclusion of additional pertinent sources. The data extracted from the selected articles were organized using a systematic approach. Key findings, concepts, and themes were identified, and a preliminary conceptual map was constructed to establish connections between different topics and subtopics. This approach facilitated the identification of overarching patterns and trends within the literature, allowing for a comprehensive understanding of the subject matter. Alongside literature research, we have applied the Delphi method to develop and refine the conceptual map. The relationship between those two lies in their potential complementary use within certain decision-making processes. The Delphi method is a structured and iterative technique that involves gathering input from a group of experts and achieving convergence in their perspectives. It aims to reach consensus or make informed predictions through multiple rounds of anonymous feedback and controlled communication. Therefore, we gathered experts from some of the

different fields identified during literature study and interviewed them. Their range of expertise included a deep knowledge in materials and management of critical components (such as permanent magnets), awareness of the environmental regulatory world and of the Life Cycle Assessment (LCA) technique, de-manufacturing and end-of-life opportunities. Through this inquiry, we were able to expand the topics and collect detailed information that could better lead our research. The extracted topics have been reviewed and developed via Large Language Model (ChatGPT4) to build a generalized description of concepts, exploring known relationships, and then collecting references (Bing AI). Concept maps can therefore be used as a supporting tool during the initial stage within the Delphi method to enhance and refining the understanding and communication of ideas among experts. Subsequently, maps can still serve as basis for new rounds of anonymous feedback and discussions.

### *B. Organisation of findings*

We employed a graphical analysis technique, called *concept map* or *conceptual map* to organise the information collected. A concept map is a visual representation of interconnected concepts using arcs that depict the relationships between the concepts. The arcs can be lines or arrows, and their thickness can indicate the importance or strength of the relationships. Concept maps are often used as tools for learning and organizing information, as they grant a clear and structured visualisation of conceptual relationships. They can be used in various contexts such as education, strategic planning, problem-solving, and knowledge representation. The mapping process involved analysing the extracted data and identifying the key recurring themes and critical areas of focus. The conceptual map (Figure 1) constructed in this study represents the interconnectedness of various topics related to the environmental issues, European laws and regulations, and raw materials supply in the medical devices industry. The links between nodes illustrate the relationships and connections between the various topics. These connections can be based on similarities, dependencies, causal relationships, or any other relevant associations identified in the literature. By visually representing relationships and hierarchies between different topics, the map helps to provide a comprehensive overview of the subject matter. It allows researchers and readers to grasp the interdependencies between different themes, identify central concepts, and understand the broader context of the issues addressed. The analysis focused on identifying the major concerns, assessing the effectiveness of existing regulations, and exploring potential solutions and innovations

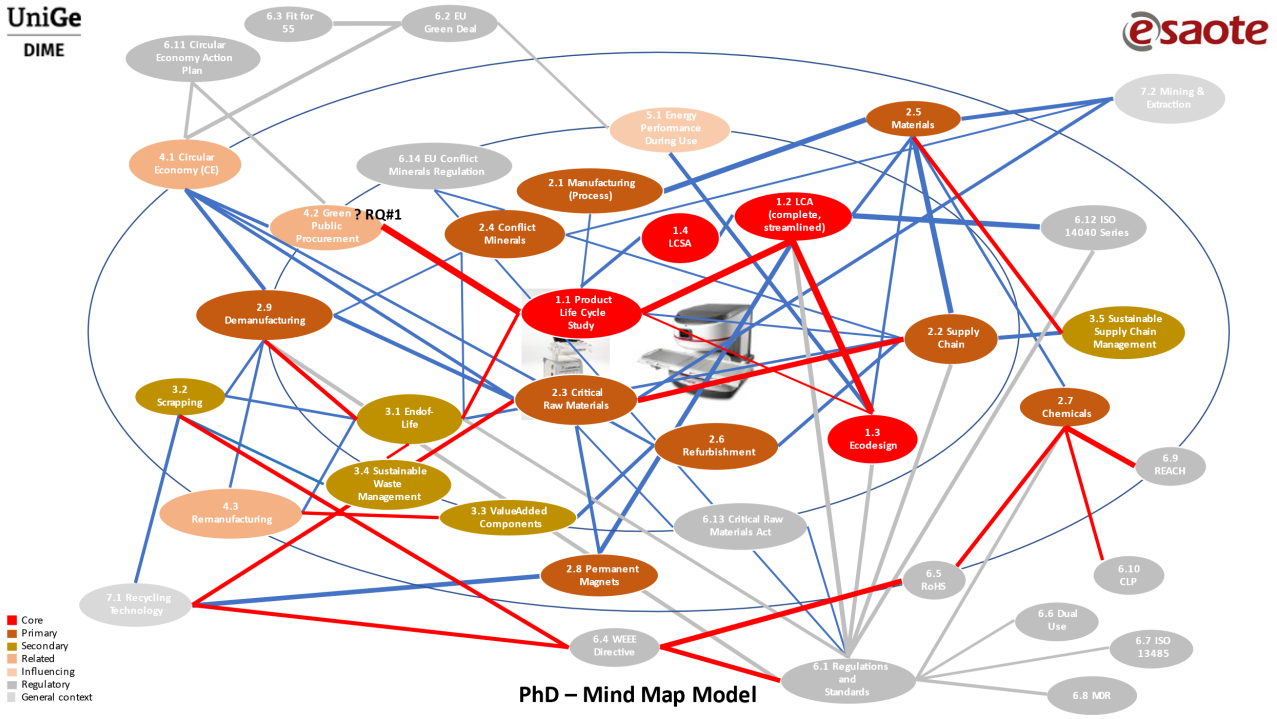


Figure 1 – Conceptual Map

The literature search made us extend the map, introducing new topics and finding new links between them. Using this map model, we defined the study perimeter and the research journey to formulate appropriate research questions to be listed in an industrial research agenda.

## III. DISCUSSION

### *A. The analysed key-areas*

The aim of our research is to deepen the knowledge on the medical devices industry and create a basepoint foundation in this sector. We divided the area of the study in three zones, whose distance from the centre is related to the importance of the topic. In the outer part we put topics acting as frame of the research, which are beyond our direct control or ability to influence. Moving to the mid part, we encountered topics more closely related to our study objectives, that exerted a great influence on it. Finally, in the central part of the map we allocated the core topics, which serve as the focal points of the activity. This layered map structure allowed us to visualize the varying degrees of influence and significance of different topics within our research framework.

### *B. Research phases*

We organised our research in three phases, since it was the best way to accomplish our goals. Firstly, we concentrated on the European policies and regulations on the environment, to build a solid knowledge in the regulatory field. Then, we analysed the medical devices field, to understand what types of research had already been conducted and the findings until now acquired. Finally, we focused on the scientific and technological framework, to evaluate possible tools that would be useful for our purposes.

#### *1. Study of the healthcare industry*

Healthcare industry is placing great emphasis on social, economic, and environmental sustainability[11],[12] since it has a significant impact on these spheres. Environmental sustainability in the health sector can become a connection between environmental operations and enhanced healthcare services. Despite the relevance of the medical devices (MD) industry in the health sector, its environmental problems have only recently started to be discussed[11]. Production and use of MD demand abundant amounts of energy and natural resources, and disposal requires extreme attention considering diversity of composition. Given this significant consumption of goods and services, recent studies have examined the indirect environmental, human health, and economic impacts attributed to the large volumes of materials, devices, and services utilized by the healthcare system. These studies assess for instance that at their end of life, these products generate large amounts of solid waste, and provide examples of sustainable strategies that can be applied to the healthcare system. Re-manufacturing, recycling, and optimizing waste treatment processes are valid options for sustainability, but we must remember the biocompatibility of any new material.

#### *2. Study of European environmental policies and regulations*

We paid great attention to European regulations in this field, as it is mandatory to be compliant with them. We divided this analysis into two parts: in the first one we concentrated on the European policies framework, as we considered the EU Green Deal, the Fit for 55, and the Circular Economy Action Plan, and others; in the second one we shifted on the laws which regulate this manufacturing sector, from the environmental point of view. It is important to note that the legislation is broad, and it encompasses more than one sector, as it is referred to industry in general; moreover, there are also rules specifically related to healthcare manufacturing. As previously mentioned, we initially focused on the European policies, so we had a clear vision on the European proceedings and the future perspectives. We found as most important measures the European Green Deal[13] (EGD), the new plan which "*aims to transform the EU into a fair and prosperous society with […] a competitive economy*"[14], announced in 2019. The main goals of the EGD are a net carbon neutral European Union by 2050 and a decoupling of economic growth and resource use. The EGD is not a law, but a general policy strategy, outlining the ambitions and goals in different policy sectors. For its implementation, existing regulations and standards will be revised over the next few years and new laws and directives will be developed and implemented[15]. Strongly related to the Green Deal there is another EU climate change package known as Fit for 55[16]: it was presented on 14th July 2021 under the Green Deal[17]. It contains different proposals that aim to improve EU legislation in environmental field, and new measures that can ensure the achievement of carbon neutrality. Another important aspect of the European legislation about the environment is the

Circular Economy Action Plan[18], initially published by the European Commission on 11th March 2020. It serves as a roadmap for the EU's circular economy strategy and outlines the actions and initiatives to be undertaken in the coming years. The plan builds upon previous initiatives and policies related to the circular economy and sets forth a comprehensive framework for transitioning towards a more sustainable and circular economic model. It is also part of the European Green Deal. After reviewing the main EU policies, we moved to the EU legislation. This part of our study took a lot of time, because of the great number of laws that regulate the industrial frame including healthcare sector. In fact, some of them are more general, and they encompass all the fields of manufacturing, rather than others, which are specifical of this field. Among the significant EU regulations that we explored are REACH[19],[20], RoHS[21],[22], and CLP[23],[24]. These regulations play a vital role in ensuring the safety, environmental sustainability, and quality of products across various industrial sectors, not limited to healthcare alone. There are also other important regulations about medical devices, and the main one is the Medical Devices Regulation[25],[26] (MDR), published in 2017. It sets out a series of characteristics that a medical device must have to be compliant. Mainly, the aim of the MDR is to launch safer and more effective medical devices onto the market.

3. *Study of supply chain and raw materials issues*

The study of the supply chain poses significant challenges for business organizations as it plays a vital role in their operations. One of the primary challenges lies in establishing and maintaining an efficient and sustainable supply chain management system. This undertaking necessitates a deep understanding of the intricate networks that encompass suppliers, manufacturers, distributors, and retailers. Effectively managing these networks involves optimizing logistics, streamlining processes, and leveraging advanced technologies to enhance visibility and coordination. Within this context, it is crucial to introduce the concept of Sustainable Supply Chain Management[27] (SSCM). SSCM entails integrating environmentally and socially responsible practices throughout the entire supply chain, aiming to create a sustainable framework that promotes economic development, social well-being, and environmental protection. SSCM's importance has grown in today's business environment, driven by the increasing demands from consumers and regulators for greater environmental and social responsibility from companies. Furthermore, conducting a comprehensive analysis of the supply chain yields valuable insights into each stage of its organization. To gain a clear and holistic understanding of the topic, our study begins with a specific focus on the raw materials supply, including both conventional and critical raw materials. This examination encompasses an exploration of the laws and directives that regulate the sourcing, usage, and disposal of these materials. Understanding the environmental implications, resource availability, and ethical considerations surrounding raw materials sourcing is essential in fostering sustainability within the medical devices industry. By addressing these aspects, businesses can better navigate the challenges associated with raw materials supply and contribute to the development of a more sustainable supply chain.

4. *Study of scientific and technological framework*

At the core of the framework is the application of scientific tools to enhance the sustainability of medical devices. This involves conducting studies to assess the environmental impact of different materials, manufacturing processes, and product designs. An efficient, though challenging, approach to sustainability is the LCA (Life Cycle Assessment). LCA is a technique used to quantify the impact of a product during its whole life cycle[28],[29]. Despite the rapid rate of innovation, investment to develop new products is large and the environmental impact of devices is substantial. In an industry which is already highly regulated, further pressures on environmental design are probably not welcomed but necessary. Having a deep knowledge of the product and its impact from cradle to cradle is now important in the context of ecodesign. LCA is a tool used to evaluate the environmental impacts of a product throughout its entire life cycle, from raw material extraction to disposal. By considering the entire life cycle of a product, LCA provides a comprehensive view of the environmental impacts and allows for the identification of areas for improvement. By incorporating the supply chain into the LCA, companies can gain a better understanding of the environmental effects of their products. In detail, having an aware supply chain could potentially lead to two important consequences: first, it could be possible to select scrupulously raw materials, maybe choosing recycled or greener or less

dangerous ones; then, this could lead to a robust supply chain, less at the mercy of economic, social, and political fluctuations. Data gained from the LCA study can help ensure that products are sourced and produced in a sustainable manner. Together, LCA and a robust supply chain can help companies reduce their environmental footprint and enhance their sustainability performance.

### *C. Construction of the conceptual map*

The map (Figure 1) constructed in this study is divided into three distinct zones, each representing different levels of relevance and influence on the research objectives. The central zone of the map comprises the main topics that are directly and significantly related to the focus of the research, which in this case are the healthcare Ultrasound imaging (US) and Magnetic Resonance (MR) imaging systems. These main topics encompass the core themes, key findings, and critical aspects that are of utmost importance to the research objectives. Moving away from the central zone towards the outer zones of the map, the topics become progressively less influential to the research and have a more peripheral or superficial connection. These topics may still have some relevance to the broader context of the research, but their impact and significance are comparatively lower in relation to the central topics. Placing the main topics in the central zone emphasizes their significance and highlights their direct relevance to the research objectives. This central positioning draws attention to the core themes that are integral to the understanding and analysis of the healthcare US and MR systems, while also facilitating a focused and targeted discussion. On the other hand, the outer zones of the map accommodate topics that, although not central to the research, provide additional context or serve as supporting information. These topics may touch on related areas such as broader environmental issues, general regulatory frameworks, or raw materials supply chains that have some peripheral connection to the healthcare devices being studied. While these topics may not be the primary focus, their inclusion in the map acknowledges their potential influence and ensures a more comprehensive representation of the broader landscape surrounding the research. The division into zones within the map serves as a visual aid to guide readers in understanding the relative importance and relevance of different topics within the research context. It allows for a clear differentiation between the main themes that drive the analysis and the peripheral topics that provide additional context or supplementary information. By incorporating this zone-based approach, the map provides a structured representation of the research landscape, enabling readers to identify and navigate the central topics that hold the greatest significance while acknowledging the broader context and peripheral influences that contribute to a more holistic understanding of the subject matter. With the literature search we found a great number of topics, and we added the more important ones to the scheme, to supplement it by appropriate research topics. As the literature review progressed, every time a new topic was discovered that had relevance to the healthcare systems, it was incorporated into the map. This ensured that the map captured the breadth and depth of the research landscape, encompassing all significant aspects that influenced the study objectives. Furthermore, during the map construction, careful attention was given to establishing the appropriate links between the various topics. These links were established based on the relationships and connections identified in the literature. Whether the relationships were based on similarities, dependencies, causal associations, or any other relevant connections, the map was designed to reflect these interdependencies and provide a clear visual representation of how the different topics relate to one another. The addition of appropriate links between topics served to enhance the comprehensiveness and coherence of the map. It allowed for a more holistic understanding of the interrelationships between various themes and subtopics, illuminating the complex network of ideas and concepts in the research domain. This approach resulted in a comprehensive map that effectively represents the multifaceted nature of the healthcare US and MR systems, their environmental considerations, European regulations, and raw materials supply chain.

## IV. CONCLUSIONS

These findings have implications for stakeholders across the healthcare industry. Manufacturers like Esaote S.p.A. can leverage these insights to drive innovation and develop more sustainable products and manufacturing processes. Regulatory bodies can use these findings to refine and strengthen existing regulations, while policymakers can implement measures that encourage sustainable practices and promote a circular economy. It is important to note that while the findings provide valuable insights, there are certain limitations to

consider. The research is based on the available literature and may not encompass every aspect of the topic. Additionally, the dynamic nature of the healthcare industry means that new technologies, regulations, and supply chain practices may emerge, necessitating further research and continuous monitoring. Furthermore, medical devices could be also considered as Product-Service System (PSS) if integrated with a series of services that go beyond the physical product itself, providing a more sustainable consumption and production paradigm[30]. Starting from a limited number of fundamental concepts, we have delineated a new set of 37 concepts and a total of more than 70 connections. Considering the dimensionality of the problem, a conceptual map was the best way to visualise it all. The research agenda is around dominant areas such as sustainability, regulatory, LCA, materials and permanent magnets. In conclusion, the findings of this research highlight the environmental impact, European regulations, and raw materials supply chain challenges associated with the imaging medical devices. By understanding and addressing these findings, stakeholders can work towards a more sustainable and environmentally responsible approach to the development, use, and disposal of these medical devices, ultimately contributing to a greener and more socially responsible healthcare industry.

## V. REFERENCES


[1] G. Seliger, in *Sustain. Manuf.* (Ed.: G. Seliger), Springer Berlin Heidelberg, Berlin, Heidelberg, **2012**, pp. 3–8.

[2] K. R. Haapala, F. Zhao, J. Camelio, J. W. Sutherland, S. J. Skerlos, D. A. Dornfeld, I. S. Jawahir, A. F. Clarens, J. L. Rickli, *J. Manuf. Sci. Eng.* **2013**, *135*, 041013.

[3] F. Tonelli, S. Evans, P. Taticchi, *Int. J. Bus. Innov. Res.* **2013**, *7*, 143.

[4] M. Lieder, A. Rashid, *J. Clean. Prod.* **2016**, *115*, 36–51.

[5] J. Cifuentes-Faura, *Air Qual. Atmosphere Health* **2022**, *15*, 1333–1340.

[6] R. A. Grifa, G. Pozzoli, *Microchem. J.* **2019**, *148*, 568–572.

[7] M. Gudeppu, S. Sawant, C. G. Chockalingam, P. S. Timiri Shanmugam, in *Trends Dev. Med. Devices*, Elsevier, **2020**, pp. 135–152.

[8] F. P. Carvalho, *Food Energy Secur.* **2017**, *6*, 61–77.

[9] M. Girtan, A. Wittenberg, M. L. Grilli, D. P. S. de Oliveira, C. Giosuè, M. L. Ruello, *Materials* **2021**, *14*, 1826.

[10] M. M. Grime, G. Wright, in *Wiley StatsRef Stat. Ref. Online* (Eds.: N. Balakrishnan, T. Colton, B. Everitt, W. Piegorsch, F. Ruggeri, J.L. Teugels), Wiley, **2016**, pp. 1–6.

[11] M. Lenzen, A. Malik, M. Li, J. Fry, H. Weisz, P.-P. Pichler, L. S. M. Chaves, A. Capon, D. Pencheon, *Lancet Planet. Health* **2020**, *4*, e271–e279.

[12] J. D. Sherman, C. Thiel, A. MacNeill, M. J. Eckelman, R. Dubrow, H. Hopf, R. Lagasse, J. Bialowitz, A. Costello, M. Forbes, R. Stancliffe, P. Anastas, L. Anderko, M. Baratz, S. Barna, U. Bhatnagar, J. Burnham, Y. Cai, A. Cassels-Brown, A. F. P. Cimprich, H. Cole, L. Coronado-Garcia, B. Duane, G. Grisotti, A. Hartwell, V. Kumar, A. Kurth, M. Leapman, D. S. Morris, M. Overcash, A. G. Parvatker, D. Pencheon, A. Pollard, B. Robaire, K. Rockne, B. L. Sadler, B. Schenk, T. Sethi, L. S. Sussman, J. Thompson, J. M. Twomey, S. H. Vermund, D. Vukelich, N. Wasim, D. Wilson, S. B. Young, J. Zimmerman, M. M. Bilec, *Resour. Conserv. Recycl.* **2020**, *161*, 104882.

[13] J. A. Samper, A. Schockling, M. Islar, *Polit. Gov.* **2021**, *9*, 8–16.

[14] European Commission, **2020**. Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions - The European Green Deal. P.2

[15] Fetting, C., **2020**. The European Green Deal, ESDN Report, December **2020**, ESDN Office, Vienna

[16] Fit for 55, *https://www.consilium.europa.eu/en/policies/green-deal/fit-for-55-the-eu-plan-for-a-green-transition/*

[17] M. Köhl, S. Linser, K. Prins, A. Talarczyk, *For. Policy Econ.* **2021**, *132*, 102596.

[18] Circular Economy Action Plan, *https://www.europarl.europa.eu/news/en/headlines/society/20210128STO96607/how-the-eu-wants-to-achieve-a-circular-economy-by-2050*

[19] D. J. Andrew, S. L. Wright-Williams, in *Regul. Toxicol. Eur. Union* (Eds.: T. Marrs, K. Woodward), The Royal Society Of Chemistry, **2018**, pp. 468–504.

[20] REACH, *https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive_en*

[21] V. Balaram, U. Rambabu, M. R. P. Reddy, N. R. Munirathnam, S. Chatterjee, *MAPAN* **2018**, *33*, 329–346.

[22] RoHS, *https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive_en*

[23] Paola Di Prospero Fanghella, Tiziana Catone, *Ann Ist Super Sanità* **2011**, *47*, 126–131.

[24] CLP, *https://echa.europa.eu/regulations/clp/understanding-clp*

[25] T. Melvin, M. Torre, *EFORT Open Rev.* **2019**, *4*, 351–356.

[26] Raga Padmasri, Deepika Majety, Sujatha Katru, Jaya Prakash, Veluchuri Kumar, Ravi Kumar, Reddy Juturi, New Era in Medical Device Regulations in the European Union, *Pharmaceut. Reg. Affairs* 10, **2021**, 234

[27] P. Taticchi, P. Garengo, S. S. Nudurupati, F. Tonelli, R. Pasqualino, *Int. J. Prod. Res.* **2015**, *53*, 6473–6494.

[28] M. Z. Hauschild, R. K. Rosenbaum, S. I. Olsen, Eds. , *Life Cycle Assessment: Theory and Practice*, Springer International Publishing, Cham, **2018**.

[29] M. A. Curran, Ed. , *Life Cycle Assessment Handbook: A Guide for Environmentally Sustainable Products*, Wiley, **2012**.

[30] Flavio Tonelli, Paolo Taticchi, Elena Starnini Sue, *WSEAS TRANSACTIONS on BUSINESS and ECONOMICS* **2009**, *6*, 303–319.