Simplification of Administrative Burden in Environmental Legislation: Response to EC Call for Evidence

Brussels, 10 September 2025

MedTech Europe envisions a future where healthcare systems are environmentally and financially sustainable, equitable and resilient to future crises.[1] In this future:

1. The improved link between climate, sustainability and health across all political areas has led to health systems that are better at preventing diseases, minimising interventions, optimising the patient pathway and increasing the number of healthy life years of European citizens.
2. The healthcare sector has embedded sustainability across operations, innovations and supply chain.
3. A competitive medical technology industry is providing safe, innovative, and sustainable solutions for ever better patient outcomes.
4. Such modernised healthcare systems serve patients within an overall resource-efficient, digitally enabled and competitive economy that fuels Europe's sustainable prosperity and competitiveness and leverages the EU climate goals to drive benefits for people, planet and business.

Currently, the barriers to such a future remain manifold. They include a fragmented regulatory framework, inconsistent definitions and standards, a lack of harmonised tools and methodologies, missing safer alternatives, financial, technological and clinical limitations, staff and skills shortages, overall system inefficiencies and increased strains on complex global supply chains besides geopolitics.

In this call for evidence response, we focus on the potential of simplifying administrative burden stemming from EU environment policies affecting the MedTech sector without affecting the pursued environmental objectives and without compromising patient safety as required by the strict sector specific regulatory system of Regulations (EU) 2017/745 regarding Medical Devices (MDR) and (EU) 2017/746 on *in vitro* diagnostic Medical Devices (IVDR).

We welcome the possibility to share feedback and relevant evidence for the upcoming initiative on Simplification of Administrative Burden in Environmental Legislation and structure our response into the following parts:

(1) General comments on the purpose and system boundaries of EU environmental reporting and administrative requirements
(2) Key simplification levers regarding EU environmental administrative burden for the MedTech Sector
(3) Specific recommendations on reducing administrative burden of key EU environmental policies affecting the European medical technology sector
(4) Conclusions
(5) Supporting Evidence

Annex 1: Overview of EU environment regulations affecting the Medical Technology Sector and their wider regulatory landscape

Annex 2: Overview of the design cycle steps required for a medical technology

[1] EU Prosperity and Competitiveness: MedTech Europe Recommendations for Implementing the EU Green Deal in Healthcare, November 2024

1. General comments and recommendations on defining the purpose and system boundaries of EU environmental reporting and administrative requirements

Administrative and reporting requirements in EU regulations serve essential purposes, ensuring transparency, accountability, and legal certainty for businesses, consumers, and governments. These requirements help maintain fair competition, protect consumer rights, and enforce regulatory, environmental and social standards. By collecting and analysing data, regulators can monitor compliance, detect risks, and adapt policies to evolving economic and technological landscapes. Furthermore, standardised reporting enhances trust in markets, reducing fraud and promoting investor confidence.

However, excessive bureaucracy can become a burden, especially for small and medium-sized enterprises (SMEs), limiting competitiveness and economic resilience. High compliance costs, time-consuming procedures, and complex documentation can divert resources from innovation, expansion, and job creation. In highly regulated industries, such as the medical technology sector, businesses may struggle to compete globally if administrative and overlapping EU requirements exceed those of other regions and also unintentionally inhibit patients' access to life saving and life sustaining technologies.

Striking the right balance is crucial. Simplifying procedures, leveraging digital solutions, and applying proportionality principles can reduce administrative burdens while maintaining oversight. Ultimately, well-designed reporting requirements should enhance market efficiency and sustainability without stifling economic dynamism or discouraging investment in the European economy.

Establishing proper system boundaries and implementing them consistently throughout the EU policy acquis across different policy domains bears the highest simplification potential and should be the overall priority: One of companies' biggest challenge in compliance preparations are inconsistencies in EU legislation ranging from definitions, such as of "economic operators" or "placing on the market" or "making available", which require costly parallel compliance tools, financial and human resources. In addition, the cumulative burden of implementing many EU regulations in parallel and under short timelines stifles companies' innovation capabilities and global competitiveness.

MedTech Europe sees significant horizontal administrative burden reduction potential in agreeing on system boundaries, such as the following, and their consistent implementation throughout the entire EU environment policy acquis:

- **Preserving the EU Single Market and free circulation of goods, services, people and capital should guide EU policy making**. Diverging requirements in the EU Single Market hamper Europe's sustainable prosperity and competitiveness.[2] The TRIS Directive (EU)2015/153520 should be properly enforced and its notification process strengthened (see also Commission Report on the Operation of the Single Market Transparency Directive from 2016 to 2020 (COM(2022) 481 final).
- **The EU New Legislative Framework (NLF)[3] should be Europe's product policy blueprint and consistently applied in EU legislation**: the upcoming revision of the NLF is an opportunity to

[2] MedTech Europe response to EC Call for Evidence on the EU Single Market Strategy
[3] Please see New legislative framework - European Commission

further align EU environmental policies with the NLF.[4] While, for example, well implemented in the new EU Ecodesign for Sustainable Products Regulation, we observe important departures from the common understanding that the NLF has harmonised in key Green Deal files, such as the EU Batteries Regulation and Packaging and Packaging Waste Regulations, thereby diluting product requirements in the Single Market and increasing administrative and reporting burden on companies.

- **The EU Standardisation System should be revived**: Harmonised standards ensure consistency, interoperability, and legal clarity across the EU, reducing trade barriers and compliance costs. They enhance product safety, quality, and consumer trust while fostering innovation and fair competition. By aligning regulations, businesses can access larger markets more efficiently, boosting economic growth and the EU's global competitiveness. The EU's standardisation system needs urgent reform.
- There should be **one standardised reporting tool for implementing EU reporting requirements** throughout the entire policy acquis to increase reporting efficiency and reduce compliance costs.
- **Digitalisation should be acknowledged as a key lever of administrative burden reduction and efficiency:** digital tools for compliance should replace outdated paper requirements and take priority for implementing reporting, information and labelling obligations: For example, manufacturers of medical technologies are obliged to provide instructions for use (IFUs) to users. The recent step to broaden the possibility of electronic instructions for use are a positive example that besides reducing administrative burden reinforces environmental ambitions through significant savings of paper. It should inspire further action. The new ESPR Digital Product Passport (DPP) bears further potential for harmonisation of reporting and information requirements while it should not duplicate sector specific regulatory requirements, notably the sector specific EUDAMED database. We recommend a unified architecture with sector specific modules (a harmonised DPP core backbone with sectoral modules) to ensure interoperability and reduce duplication.
- **Realistic, patient centric and economically viable Green Deal transition pathways are needed.** They should allow sufficient transition time for medical technology manufacturers, including their manufacturing supply chains, in order to enable uninterrupted access to medical technologies for patients and practitioners alike, during the transition to net-zero. Misaligned compliance deadlines between the sectorial legislations (MDR and IVDR) and environmental compliance deadlines cause massive administrative burden since product changes or supplier switches due to environmental requirements trigger certain lengthy and complex MDR/IVDR renotification, requalification and education requirements. At worst, they cut off patient access to life saving and life sustaining medical technologies.
- **Commission guidance and FAQ documents should, as a rule, be available at least 12 months before the application date** of newly introduced requirements to support companies in their timely compliance preparations and the preservation of the functioning of the EU internal market.
- **Confidential business information, IPR and know-how must be protected and not be compromised through reporting or information requirements**: the newly introduced One-

[4] MedTech Europe response to EC call for evidence on revision of the New Legislative Framework, September 2025: "Alignment of definitions is key: The definition of 'manufacturer' in the Batteries Regulation, for example, reads similar to the definition of 'manufacturer' in the Commission Blue Guide on the Implementation of EU Rules 2022, however adds on the term "or puts it into service for its own purposes", thereby creating significant confusion amongst economic operators. Besides, recent sustainability and digital legislation has added new roles (such as „independent operator", „deployer" or „open-source steward") and new lifecycle concepts (including „substantial modification" and „refurbishment/remanufacturing"), but without common definitions. Developing clear and uniform terminology bears the potential to further strengthen legal certainty and to facilitate compliance throughout the EU."

Substance-One-Assessment package is a positive example of streamlining the evaluation of chemicals assessments across EU chemicals regulations. However, the new common data platform[5] must not compromise confidential business information or create duplication and inconsistencies with the sector specific EUDAMED database established by MDR and IVDR.

- **Screen and slim language requirements according to need and proportionality** to boost efficiency and prevent unnecessary administrative burden.
- **Keep administrative fees, if any, to the minimum necessary**: The EU Chemicals Agency's fee regulation for example poses challenges, particularly for small and medium-sized enterprises (SMEs). High fees create financial burden, limiting market access and innovation. Complex fee structures and administrative hurdles increase compliance cost, reducing competitiveness. This could entail a negative spiralling effect of discouraging new entrants while consolidating market power among larger companies and very likely stifling innovation.

2. Key simplification levers regarding EU environmental administrative burden for the MedTech Sector

The medical technology sector is a densely regulated sector (see Annex 1: Overview of the regulatory landscape of EU Medical Technology manufacturers, including relevant EU environment policy legislation and their broader regulatory environment).

The call for evidence stresses the need to reduce administrative burden stemming from environmental legislation in the areas of the circular economy, industrial emissions and waste management. It suggests several concrete measures, including the following, which MedTech Europe fully supports:

- Rationalising reporting/notification obligations, for example, the discontinuation of the SCIP (substances of concern in products) database under the Waste Framework Directive;
- Harmonisation of the provisions for authorised representatives for extended producer responsibility (EPR) in each Member State where a producer sells a product falling under EPR rules and on facilitation of EPR reporting;
- Streamlining reporting obligations, removing double requirements to report, promoting further digitalisation of reporting in the area of circular economy, industrial emissions and waste management, while maintaining the policy objectives;
- Addressing permitting challenges relating to environment assessments based on experience recently gained such as under the Net Zero Industry Act.

In general, MedTech Europe observes **five recurring key triggers of administrative burden for the MedTech sector**. Below table identifies these triggers and lists **additional recommendations for administrative burden reduction measures** across these legislations while preserving environmental and human health and the EU's safety ambitions for medical technologies:

[5] Please see Article 22 of Proposal for a Regulation establishing a common data platform on chemicals - European Commission, December 2023 and MedTech Europe position paper

TRIGGERS OF ADMINISTRATIVE BURDEN	HORIZONTAL RECOMMENDATIONS FOR ADMINISTRATIVE BURDEN REDUCTION
1. **Incoherence of EU legislation** (such as diverging definitions, terminologies, methodologies, or misaligned compliance deadlines of environmental requirements and MDR/IVDR requirements)	• Take MedTech specificities and the sector's regulatory system set by MDR/IVDR into account from the outset in the design of EU environment legislation • Grant upfront Medtech specific transitional arrangements in EU environment legislation to align environment compliance deadlines with the sector's regulatory system and practical realities, such as supply chain complexity or patient safety requirements; in particular, enact sufficient time in EU environment legislation to transition to safe and better performing alternatives that aligns with MDR/IVDR timelines for regulatory re-approval (please see Annex 2) • Allocate strategic investments into building sustainable, climate resilient healthcare systems in the Multiannual Financial Framework (MFF)
2. **Fragmentation of requirements across Member States and across different policy domains**	• Revive the EU Single Market and secure the functioning of the internal market (i.e., through better harmonised environmental regulations across EU Member States and a consistent implementation of the New Legislative Framework across different policy domains) • Seek alignment with policy makers on a MedTech Green Public Procurement Framework
3. **Untapped synergies between the sustainability and digital transitions**	• Replace outdated paper-based processes by digital compliance tools • When deploying digital tools for compliance, ensure coherence with the sector specific tools, notably EUDAMED • Allow manufacturers to provide information digitally (e.g., in the new Packaging and Packaging Waste Regulation and secondary legislation derived from it); physical labelling requirements should only apply if necessary to avoid serious risks • Remove the duplication of reporting *tools*, e.g. Digital Product Passport under the Batteries Regulation and ESPR, Article 33 notifications via REACH and SCIP database).
4. **Complexity and fragmentation of reporting requirements**	• Apply the "one environmental parameter - one reporting" principle to better harmonise reporting requirements and keeping administrative to the minimum necessary (e.g., removal of reporting overlaps stemming from the above-mentioned parallel application of the EUDR, CSRD, CS3D, Batteries, Packaging and Sustainable Products Regulations) • Introduce a "one stop shop digital EPR gateway at EU level" for EPR registration and reporting; these obligations under Extended Producer Responsibility (EPR) schemes should be streamlined and harmonized across Member States.
5. **Better international alignment**	• Reinforce the global harmonisation of standards for waste, circularity and secondary raw materials with respect of the quality and safety for patients and healthcare practitioners • Pursue a proactive green diplomacy agenda to promote global carbon pricing and international commitments for tripling renewable energies and energy efficiency

3. Specific recommendations for administrative burden of key EU environmental policies affecting the European medical technology sector

We further specify the sector specific issues arising from key EU environment legislations of particular relevance to the MedTech sector, i.e.:

- Directive 2008/98/EC – Waste Framework Directive
- Directive 2012/19/EU – WEEE (Waste from Electrical and Electronic Equipment)
- Regulation (EU) 2025/40 – PPWR (Packaging and Packaging Waste)
- Regulation (EU) 2023/1542 – BWBR (Batteries and Waste Batteries)
- Regulation (EU) 2024/1781 – ESPR (EU Ecodesign of Sustainable Products)
- Regulation (EU) 2023/1115 – EUDR (Deforestation-Free Products)
- Regulation (EC) No 1907/2006 – REACH (Registration, Evaluation and Authorisation of Chemicals)
- Stockholm Convention on Persistent Organic Pollutants and Regulation (EU) 2019/1021 (POPs)
- Regulation (EC) No 1272/2008 – CLP (Classification, Labelling and Packaging of Substances and Mixtures)
- Directive 2011/65/EU – RoHS (Restriction of Certain Hazardous Substances in EEE)
- Regulation (EU) 528/2012 – Biocidal Products Regulation (BPR)

These build on the previously outlined administrative burden triggers and showcase the complexity of the environment and health policy interface while underlying the importance of a holistic simplification approach for the MedTech sector in the interest of EU prosperity, sustainability and patient safety and access to medical technologies to diagnose, treat and cure diseases.

Law: Directive 2008/98/EC – Waste Framework Directive
Issues that trigger administrative burden: • The medical technology industry is undertaking efforts to reduce waste and environmental footprints. Improving sustainability must go hand in hand with safe and clinical effectiveness for patients. • Duplication of reporting requirements due to mandatory SCIP database: Medtech companies supplying articles containing substances of very high concern (SVHCs) on the Candidate List present in a concentration above 0.1% weight by weight (w/w) need to submit their input to the Substances of Concern In Products (SCIP) database. The SCIP database was created to make that information available mainly to waste operators and consumers. For MedTech sector this is of limited use due to the specific (hazardous) nature of most of our waste stream. SCIP was also meant to prevent SVHCs from hampering recycling options, which for the same reason is not applicable to most of MedTech products. • Risk of misinterpretation of complex Bill-Of-Material (BOM) data by authorities or the public. • An example of the scope 3 emissions data gathering and verifiability complexity is that most medical technology products cannot be disposed of in the same manner as traditional consumer products due to issues with infective or biohazardous waste. Disposal of medical waste tends to be highly regulated at the local level, and not always in a uniform way. Additionally, much of the waste created is collected at point of care settings, including hospital and physician offices, which our industry does not control, but which can enable large scale collection and potentially recycling, where appropriate and where possible due to government and regional infrastructures and/or mandates. MedTech companies are committed to being part of the solution and is working with stakeholder partners to identify opportunities for collaboration and to help promote education and uptake of recycling efforts. We support technological advances that lead to improved re-use and recycling of products and packaging waste but while maintaining clinical efficacy and patient safety as the North Star. • We also encounter administrative burden with the related Waste Shipment Regulation (EU) 2024/1157: The notification approval process is lengthy and complex (can take 6 to 9 months) with

annual renewals adding onto the difficulty. Additional administrative burden stems from a lack of standardised templates, guidance across different countries and different local language requirements.
Possible solutions: • Delete SCIP database: The obligation is redundant and duplicative with other tools, i.e., Digital Product Passport under ESPR, article 33 REACH notifications or through REACH Safety Data Sheets being collected and shared with business partners along value chains; strive for a collaborative process to map and analyse all relevant data requirements to support a standardised proposal for regulatory compliance, which would include improving supply chain data management and data gathering through the supply chain. Such coordination would help satisfy environmental and chemical legislation, encourage supply chain collaboration, and reduce administrative burdens long-term. This consultation presents an opportunity to address priorities for the DPP, including improving information flows in product value chains. • For promoting framework conditions that enable the structured and safe return of medical devices to recycling, manufacturers, clinics, waste disposal companies and authorities must be brought together. Incentives for cross-manufacturer industry solutions and funding could support the expansion of standardised recycling paths and the viability of decontamination processes and chemical recycling for MedTech waste. • Governments should establish robust recycling and upcycling programs where the output of recycled material is verifiably incorporated back into the local community infrastructure Leverage reimbursement and public procurement mechanisms to account for sustainability value creation. • Limit cross-regulation data reporting requirements • Set quality standards for secondary raw materials • Regarding the related Waste Shipment Regulation (EU) 2024/1157, we recommend uniform guidelines, templates and language requirements besides EU approvals in registered schemes, longer renewal periods, and exemptions for low-risk wastes to reduce administrative burden and encourage the recycling of these wastes. Additionally, the waste code classification needs clearer EU-wide criteria, and full digitisation through the DIWASS system to streamline notifications and enforcement, making the process more efficient and less burdensome.

Law: Directive 2012/19/EU – WEEE (Waste from Electrical and Electronic Equipment)

Issues triggering administrative burden:
• Lack of harmonisation between the EU Member States in regard to the transposition of the Directive into national legislation
  ○ Ambiguity in classification of medical technologies under WEEE categories, especially distinguishing between B2B and B2C use across Member States.
  ○ WEEE marking and return obligations are impractical for certain device types (e.g., implanted devices, devices used in sterile environments such as operating theatres).
• Regulatory inconsistencies and overlapping requirements between WEEE and ESPR, especially regarding the design of products
• Medical technologies are often designed for long-term, professional use and are not suitable for inclusion in household collection schemes. Medical waste streams are often contaminated (and hazardous).

Possible solutions: • Analogue to the recent Battery and Packaging Waste Regulations, turn the WEEE Directive into an EU Regulation. • Clarify roles and responsibilities of all WEEE actors • Provide clearer guidance on the classification of medical technologies within the WEEE scope, including consistent B2B vs B2C categorisation at EU level.

- Define harmonised treatment and return logistics for professional medical equipment to avoid fragmentation and ensure legal certainty for manufacturers.
- Remove regulatory overlaps and improve consistency: product related provisions of the WEEE Directive should be removed. This is particularly true for articles 4 and 14 WEEE. The reuse of spare parts should be consistently allowed so as to support circularity and prevent premature obsolescence of appliances. As regards trade offs between requirements of phasing out substances and requirements promoting circularity, the ability of refurbishment of medical technologies and use of spare parts therein should be enhanced.
- Provide a better harmonised level playing field for WEEE treatment, by implementing the given mandate of article 10.3 WEEE to adopt EU wide harmonised common minimum treatment standards.

Law: Regulation (EU) 2025/40 – PPWR (Packaging and Packaging Waste)

Issues triggering administrative burden:

- Legal uncertainty regarding PPWR implementation and the management of MedTech specificities:
  - Relevant EC guidance documents and secondary legislation remain pending. A high level of uncertainty regarding the recognition of MedTech specificities for implementing the new Regulation persists, such as:
    - Packaging reduction targets and space reduction may overlook the sterility and protection needs of medical technologies, risking product integrity and patient safety.
    - Reuse targets may conflict with requirements for sterility and patient safety, especially for packaging that protects single-use or implantable medical devices.
    - It remains unclear if PPWR requirements (substances of concern, recyclability, plastic recycled content, reuse, etc.) apply to packaging that is used to ship goods from outside the EU to the EU and that is discarded at the warehouse site without further use.
    - Uncertainty regarding the implementation of new substances of concern provisions and their alignment with MDR/IVDR and other relevant EU legislation (i.e., REACH) remains: Packaging of medical devices is subject to stringent quality and safety requirements and the related evaluation also covers concerns related to substance presence.
    - Packaging minimisation requirements for products already on the market risks packaging redesign that in turn is likely to result in revalidations and resubmissions under MDR/IVDR. These activities risk negatively impacting companies and also Notified bodies (additional re-registrations). Rather than minimising waste, it will generate at once the waste of already manufactured packaging components that won't be used due the redesign. This could result in supply disruptions due to the inability for some companies to afford this effort for mature products with lower margins.
    - The status of intravenous (IV) bags and syringes
  - Fragmentation across Member States: Fragmented and diverse labelling obligations across Member States increase complexity, administrative burden, and compliance risk for pan-European product distribution.
  - Lack of alignment with MDR documentation results in duplicative reporting and inefficiencies, especially for legacy devices.
- Extended Producer Responsibility (EPR):
  - The current format of EPR reporting for packaging, as well as other related legislation, such as WEEE or Batteries Regulation, is complex due to the fragmentation and variability of the reporting requirements across the EU. This can be seen in the variation of data, attributes and sub-categories required by country (material sub-types, eco-modulation extra attributes…), as well as the extra reporting demanded across Member States (i.e., France printed paper, Germany dual reporting LUCID and PRO, Netherlands is about to implement a polymer reporting system, Spain and Nordic countries require waste reduction plans…).
  - There are also requirements to report reusable transportation packaging, such as wooden pallets, a very complex requirement due to the global supply chains that allow the market to work.
  - Lastly, monthly reporting frequency proves too short and impractical.

Possible solutions:

- Safety: Packaging regulations must fully consider the unique sterility and protection requirements of medical technologies. We advocate for flexibility in packaging reduction targets and allowances for empty space optimisation of contact sensitive packaging, ensuring that device integrity and patient safety are maintained without compromising sustainability efforts. MedTech specific standards for packaging minimisation should be taken into account for PPWR implementation.
- Reuse: Clarify medical device packaging's reuse obligations and assess reuse in medical technology separately, based on public health risk and MDR classification.
- Establish a single EU-wide labelling format for packaging used in the healthcare sector, aligned with digital labelling initiatives and MDR/IVDR definitions of packaging types.
- Scope: Clarify the status of intravenous (IV) bags and syringes; clarify that packaging used to ship goods from outside the EU to the EU that is not further reused in the EU (to contain, sell or transport products) is not subject to the PPWR.
- Substances of concern: when the Commission will consider restrictions of substances of concern in packaging, we propose to assess whether those restrictions are warranted for packaging of medical devices. Consistency with MDR/IVDR, REACH, RoHS and ESPR must be ensured. REACH should be the main vehicle for substance restrictions, including packaging.
- Declarations of Conformity: The creation of declarations of conformity could be simplified if referred to a packaging type, rather than per packaging unit or part of packaging unit.
- Extended Producer Responsibility (EPR):
    - There is a need to create a homogeneous, harmonised approach to EPR requirements across the EU, with a single reporting structure that allows predictability and streamlining processes, not only for manufacturers but also at Member States' level.
    - This process should also be fully digital, to allow the reduction of the administrative burden related to the reporting.
    - For quantities placed on the market falling below a threshold, there should be a fixed fee that requires no reporting, avoiding the administrative burden that is imposed on manufacturers that need to create reports for minimal packaging placed in the market.
    - Regarding the cadence of the reporting, we recommend a quarterly or annual reporting frequency.
- Introduce a grandfathering clause for packaging of medical technologies that have already undergone MDR/IVDR conformity assessments to prevent possible shortages of medical technologies on the EU market due to reassessments.

Law: Verification requirements under Battery Regulation and PPWR

Issues:

- MDR already requires an importer and distributor verification of devices, on top of the Legal Manufacturer verification of the compliance of the device. Under the new Battery Regulation, and shortly after under the PPWR, there is and will also be additional Importer & Distributor verification required for respectively the battery and the packaging. The addition of those Economic Operator (Importer & Distributor) verifications is redundant in case the Importer and/or distributor is affiliated with the Legal Manufacturer, cumbersome and of limited added value.
- In addition, the verification requirements for batteries are particularly cumbersome in relation to the elements to be verified, since the Batteries Regulation requires to verify that the battery is accompanied by DoC and CE mark, that it is correctly labelled and that the manufacturer (and importer in case of distributor verification) complied with the obligation to indicate on the battery their name, registered trade name or trademark, their postal address and the single point of contact.
- These are unrealistic requirements for batteries that are incorporated in products, such as medical technologies, that cannot be dismantled without compromising their quality, safety and sterility.

Possible solutions:

- Rely on Legal Manufacturer compliance process and explore removing the need for importer & distributor verification
- Alternatively, allow for sampling verification
- Alternatively, allow for verification of DOC alone

Law: Labelling requirements in environmental legislation (PPWR, Battery Regulation, CRMA…)

Issues triggering administrative burden:

- Labelling requirements impose excessive burdens on the medical technology industry, due to the regulatory constraints already placed on medical devices' packaging and information disclosed, the technical complexities it entails, the waste it generates, as well as the need to re-register.
- The requirement to physically label packaging is not a viable option, especially when products are sold in many EU countries, each requiring information in their official languages.
- It is confusing and burdensome to have different labelling systems across the EU (e.g. in France, Spain, Portugal), as it creates the need to have different packaging for different markets; in addition, to the short turnaround time usually provided to comply with those labelling requirements and the complexity of tracking all the new schemes across the EU.
- Batteries:
    - For batteries incorporated in products and that are not removable and replaceable, the Commission is proposing to include the QR code on the product. This option is not feasible for medical technologies.
    - Medical technology manufacturers often do not coincide with battery manufacturers and cannot be required to affix the QR code and include information over which they have no control or responsibility. This is impractical and creating excessive burdens besides legal uncertainty.
    - Medical technologies are subject to marking and labelling requirements under the EU MDR/IVDR and, at times, due to the size, no labelling is placed on the medical technology itself – in practice, meeting the requirement may not even be feasible in practical terms for medical technologies.
- PPWR:
    - The application of some of the labelling requirements to medical technologies seems unclear: for example, it is unclear whether sorting information should be provided for packaging of medical technology and B2B packaging, since this type of packaging is not discarded by consumers but in specific waste streams, primarily in hospitals.

Possible solutions:

- Digital solutions should be allowed to label packaging in all circumstances. Unequivocal clarity should be provided on the inapplicability of sorting information requirements to packaging of medical devices and B2B packaging.
- PPWR should work as a harmonisation instrument that creates homogeneous requirements across the EU regarding packaging labelling and put an end to the uncoordinated requirements that overburden manufacturers regarding compliance.
- The Commission should use its enforcement powers against Member States introducing national labelling requirements in a timely manner to avoid exposing industry to the possibility of illegal enforcement actions.
- Battery labelling**:** no marking of products exempted from removability and replaceability requirement. Instead, digital label to be placed by battery manufacturers on documents accompanying the battery, i.e. DOC and instructions for use and safety information.

Law: Regulation (EU) 2023/1542 – BWBR (Batteries and Waste Batteries)

Issues triggering administrative burden:
• Unclear classification and reporting obligations for embedded batteries in medical technologies create compliance uncertainty, especially for legacy and multi-component systems.
• Labelling, removability, and QR code requirements are technically challenging for small, sealed, or implantable devices, potentially compromising device integrity or sterility.
• Divergent Extended Producer Responsibility (EPR) schemes across Member States increase administrative burden and may conflict with MDR/IVDR obligations and healthcare logistics.
• The transitional periods for compliance, primarily designed with consumer products in mind, are not sufficiently adapted to the healthcare industry.
• Article 47: scope of due diligence requirements
  ○ Various regulations have different due diligence requirements and scopes (e.g., CSDDD, EU Deforestation Regulation, Batteries Regulation, Conflict Minerals Regulation). Discrepancy between CSDDD, potentially aiming to limit to Tier 1, while Batteries Regulation requires full supply chain transparency starting with the raw materials.
  ○ All batteries, incl. small volumes, are in scope. Obtaining due diligence data from suppliers is especially a challenge for manufacturers of very complex but small volume equipment that does not have sufficient market leverage towards (non-EU) suppliers.
• Article 49.1(d): Chain of custody or traceability system
Tracing back to raw materials is barely feasible, especially for small volume devices. Smelters obtain raw materials from multiple sources, after which they are melted together. Traceability on the mines is almost unfeasible at this point.
• Article 50: risk management
Overlapping risk management obligations in CSDDD and the challenge that batteries are only a component for medical technology manufacturers, not core business. That means that disproportionate resources are spent on due diligence for batteries (based on overall footprint).

Possible solutions: • Promote harmonised implementation guidance across Member States to reduce fragmentation and support consistent compliance pathways for medical technology manufacturers: provide EU guidance documents and secondary legislation at least 12 months ahead of compliance deadline • Apply targeted exemptions for implantable and critical-use medical devices from removability and QR code requirements, based on risk and MDR classification. • Ensure regulatory alignment with MDR/IVDR, including clarification of roles and responsibilities for B2B medical technologies under EPR schemes. • CSDDD should be the umbrella regulation, with the scope of the Batteries Regulation following the same scope and requirements, e.g. limit to Tier 1, or refer to database TRACES as in EUDR, that would at least mean that within the EU, previous conducted due diligence of upstream actors can be leveraged. • Include volume or weight threshold or allow risk/impact-based approach (80/20 rule) to allocate due diligence resources proportionally based on risk assessment.

Law: Regulation (EU) 2024/1781 – ESPR (EU Ecodesign of Sustainable Products)
Issues triggering administrative burden: • Overlapping requirements with other EU legislation: ESPR requirements can overlap with requirements from, inter alia, MDR/IVDR, Batteries, PPWR, REACH, RoHS, WEEE, CRMA. Particular concerns exist regarding doubling information reporting, and having different formats across the legislations (i.e., negative disclosure of Substances of Concern). • Gaps in definitions: quite a number of critical definitions and standards are missing, at least for the medical technology sector. This makes compliance complex, unequal across actors, and even fail to attain the goal of the ESPR.

- Carbon footprint/LCA data are needed across regulations but the lack of regulatory consistency, ambiguity of specific requirements and missing industry standards impedes efficient data creation and reporting.
- Reporting: the reporting of unsold consumer goods is unfit for medical technologies, given that this is information that is already being reported through other means; and the discarding of unsold medical goods is for safety reasons (products are unfit for sale or have reached the end of their shelf lives). The reporting and verification places unnecessary burden on the industry.
- Broad scope may unintentionally apply to medical technologies, including those where sterility, single-use design, or clinical functionality conflict with reuse, disassembly, or energy efficiency targets.
- Durability, repairability, and recyclability criteria are difficult to apply to complex, multi-component, implantable devices or IVDs, which are subject to strict MDR safety and performance requirements.
- Lack of integration with MDR/IVDR principles risks contradictory compliance obligations and may divert resources from patient safety and innovation.
- Setting mandatory sustainability performance targets in relation to recyclability or recycled content for intermediate materials may result in conflicts between different design elements of medical technologies and its sectoral legislation (MDR/IVDR) safety and performance requirements. Some intermediate non-ferrous metals (cobalt, silver, gold, palladium) or others (aluminium, plastics) are already considered to be covered by a Delegated Acts in the forthcoming years, this may have significant impact on industry's suppliers and materials/subcomponents they provide.

Possible solutions:

- Any possible mandatory obligations under future ESPR implementing measures on medical technologies need to align with MDR/IVDR requirements, allowing ESPR requirements to complement rather than conflict with existing safety and performance standards: a number of requirements are not allowed or addressed under the sectorial legislation due to the absence of possibility for implementation for the sector (i.e., PCR in products).
- Approve of MedTech Europe's application for membership of the Ecodesign Forum
- Develop sector-specific guidance for applying ESPR criteria and methodologies to medical technologies, including risk-based approaches for life-cycle and sustainability assessments
- Information requirements: Ensure information requirements that overlap with other legislation (i.e., SoC and REACH or RoHS) have the same format (negative disclosure).
- Ensure interoperability of the Digital Product Passport (DPP) with other databases, including EUDAMED, OSOA, EPREL or SCIP as long as maintained.
- Leverage reimbursement and public procurement mechanisms to account for sustainability value creation
- Limit cross-regulation data reporting requirement

Law: Regulation (EU) 2023/1115 – EUDR (Deforestation-Free Products)

Issues triggering administrative burden:

- Data gathering from suppliers is highly difficult, time intense and costly: Supply chains in the medical technology sector affected by the Deforestation Regulation are complex and globally interconnected, often involving a multitude of different suppliers that operate across different jurisdictions and regions of the world.
  Upstream, liaising with our own suppliers has confirmed severe difficulties in retrieving the information required by the EUDR to live up to newly imposed due diligence, tracking and reporting requirements. This includes access to critical compliance information such as geolocation data. In many instances, supply chain stakeholders have simply not been able to obtain such information. This is an issue which, if persisting, risks leading to significant global supply chain disruptions, including potential paper shortages or shortages of other materials falling in scope of the EUDR.

Downstream medical technology manufacturers have faced knock-on constraints in responding to questionnaires they received by their customers in their role as suppliers to hospitals or care centers.

- The duplication of regulation impedes the efficiency and effectiveness of EUDR rules: In parallel to the EUDR, further due diligence requirements have also been introduced by other Green Deal legislations, including the Corporate Sustainable Due Diligence Directive (CS3D), the Corporate Sustainable Reporting Directive (CSRD), the EU Forced Labor Act or new EU Batteries, Packaging and Sustainable Products Regulations.
- Further scope clarifications are needed to safeguard Europe's healthcare needs and workable requirements for companies, notably SMEs: The sector still encounters important uncertainties stemming from unclear EUDR threshold provision.

Possible solutions:

- Enact realistic compliance deadlines. A phased implementation approach should be introduced with differentiated dates of application along the supply chain.
- Any shipments between EU member states should be automatically considered compliant and thus not require any additional verification by operators.
- The Commission guidance needs to be further developed to allow pragmatic implementation that minimises bureaucratic workload on manufacturers having to interact with a high number of diverse supply chain actors.
- The Delegated Act, currently under development, should be adopted as soon as possible to ensure that all R&D samples (if they are not immediately destroyed after testing), all instructions and safety information as required by applicable Union legislation (when shipped separately from the product), and any packaging materials that are intended for reuse (even when shipped separately) are excluded from the scope.
- A synchronisation of practical implementation activities with requirements stemming from the EUDR and other parallel regulations will be important to avoid isolated processes and duplication of work. The Commission Guidance paper provides first helpful reference points in this respect; however, further industry-specific concretisation and standardisation will be needed while taking time to be developed and implemented.
- There should be only one reporting obligation on one aspect to allow using human and financial resources in the most effective and efficient way. Such a "one environmental parameter – one reporting" principle should be enacted throughout the regulatory acquis applying on the MedTech sector when implementing the commitment of at least 25% administrative and reporting burden reduction in the next policy term, including the removal of reporting overlaps stemming from the above-mentioned parallel application of the EUDR, CSRD, CS3D, Batteries, Packaging and Sustainable Products Regulations.

Law: Regulation (EC) No 1907/2006 – REACH (Registration, Evaluation, Restriction and Authorisation of Chemicals)

Issues triggering administrative burden:

1: Regulatory inconsistencies:

- Medical technologies fall within the scope of REACH, thereby requiring MedTech manufacturers to assess the presence of SVHCs in articles with respect to their risk to the environment while they are regulated under MDR/IVDR for their human health performance.
- According to sector-specific legislation (MDR), REACH related changes to materials or substances that are part of a medical technology may be considered "significant change in the design" that trigger necessity for carrying out additional surveillance obligations. However, proposals for new EU environmental legislation often disregard the sector specific regulatory framework established by MDR and IVDR.
- REACH definitions are not aligned with the New Legislative Framework: In particular, the definition of "placing on the market" in REACH is not aligned with the NLF and other product legislation, such

as the new EU Sustainable Products Regulation (ESPR) or the RoHS Directive, which both are NLF-aligned. Contrary to NLF, ESPR or RoHS, a substance restriction under REACH bans the making available of articles already placed on the EU market.

- REACH is the EU's horizontal chemicals framework harmonising the registration, evaluation, restriction and authorisation of chemicals. However, we observe the trend of other environmental legislation to increasingly include chemical requirements and/or mandates to set new substances restrictions in parallel to REACH. This is for example the case for ESPR (that also extends the concept of "substances of very high concerns" to "substances of concern"), the new Batteries Regulation (BBWR) and the new Packaging Regulation (PPWR).
- Where full phase out of a substance is required, chemicals legislation also comes in conflict with circular economy ambitions by limiting the refurbishment and reuse of used components as spare parts for repair, maintenance or in the manufacture of new devices.

2: Practical feasibility of REACH requirements

- Sufficient timelines for transitioning to safer and better performing alternatives: MDR and IVDR establish lengthy and complex regulatory processes. However, when new REACH restriction or authorisation requirements are in the making, these sector specific realities are often not known and/or taken into account. Hence, suggested compliance deadlines with new REACH requirements do not automatically take account of MDR/IVDR compliance obligations and timelines (as specified in Annex 2 of this paper).
- Supply chain complexity: Upstream/downstream proactive communications are not working, supply chains are very complex and obtaining information from MedTech suppliers is difficult, time consuming and costly. MedTech manufacturers supply chains can be up to 30 tiers from materials to the final device. It is not uncommon for routinely used devices to have hundreds and thousands of different components. There are 2 million different medical technologies available for preventing disease, treating and curing patients.
- Risk of regrettable substitution, cost of reformulation and redesign: Substances affected by REACH often require reformulation, redesign, revalidation and recertification under MDR/IVDR. This is particularly problematic for legacy devices or where biocompatibility is hard to replicate. Candidate alternatives are often substances that by themselves are under consideration to be restricted with the imminent risk of regrettable substitution.
- Legal uncertainties regarding the definitions of "controlled conditions" in the definition of "scientific research and development".

3: Reporting burden and uncertainty in long term planning

- The continuous tracking of substance classifications and reclassifications under environmental and human health legislation is burdensome while projected to exponentially grow until 2030.
- REACH updates are frequent (e.g., the SVHC list is updated twice a year) and ECHA implementation processes are increasingly lengthy and complex (e.g., PFAS restriction evaluation), thereby creating regulatory and legal uncertainty.
- Parallel chemicals lists, e.g., under REACH, RoHS, Stockholm Convention, cause confusion and fuel further legal uncertainty.
- This impairs long term product development, R&D investments, material planning strategies and most importantly, access to medical technologies for patients and healthcare professionals.
- Grouping of substances: we see an increasing trend to group chemicals (e.g. PFAS, Bisphenols, PVC, etc). Such a grouping approach risks 1) lack of differentiation in risk-level, e.g. some of the chemicals within that group may carry less risk than others (e.g. fluoropolymers vs other PFAS; BPA vs other structurally-related Bisphenols), 2) potential for regrettable substitution – sometimes the alternative to a given substance is another type of chemical – e.g. PFAS is one example, and 3) when substances are grouped together, this makes the data collection and assessment a much lengthier and complicated process both for industry and regulators (e.g. PFAS, Bisphenols, etc.), rather than focusing on the specific issue/chemical of concern.

Possible solutions:

- The medical technology industry is committed to the highest standards of chemical risk management measures and is working with suppliers to continuously improve the performance, safety and efficacy of our products and processes. While boosting innovation for materials, patient outcomes and the safety or performance of medical products should not be compromised.
- The upcoming REACH review is an opportunity to better align the EU's horizontal chemicals framework REACH with the sector specific regulatory system set in place by Regulations (EU) 2017/745 on MDR and (EU) 2017/746 on IVDR. We recommend introducing sector specific arrangements in the forthcoming REACH reform, including at least an upfront standard derogation period from new REACH restrictions that is aligned with the average duration of MDR/IVDR regulatory compliance process timeline (please see Annex 2 timeline). More specifically:
    - For any new restriction and authorisation of a substance used in a validated medical technology, the revised REACH Regulation should lay down a realistic and appropriate derogation period of at least 10 years for new products, which should also include their manufacturing processes, imports, and supply chain. New restrictions and authorisations should not apply on existing products already placed on the market. Alternative options, i.e., allowing the continued use of a restricted substance in MedTech where alternatives are not available and environmental emissions are controlled, should be considered.
    - To make use of such derogations, a company specific management plan could be presented to the EU's Chemicals Agency and/or competent national authority on an annual basis, including details on the conditions of use and safe disposal.
    - A review clause should be included to re-evaluate the transition deadline two years before the expiry of the granted derogation. To give industry the necessary predictability, a derogation should remain valid until the review process is completed.
    - The introduction of substance restrictions should be accompanied by an enabling R&D framework that supports medical technology manufacturers in the challenge of finding use specific, fit-for-purpose alternatives that are also satisfying the regulatory requirements such as the MDR/IVDR.
- For REACH restrictions of substances and mixtures in articles, the definition of "placing on the market" shall be aligned with the NLF for products.
- REACH shall remain the EU horizontal chemicals framework. Parallel new substance provisions (i.e., in the Batteries or Packaging Regulations), should be removed/merged into REACH.
- Workable supply chain communication obligations should be developed (i.e., Article 33 REACH in its present form does not work).
- Legal certainty for Research Use Only (RUO) Products should be improved.
- As additional tasks are being transferred to the EU Chemicals Agency (ECHA), the agency needs to be adequately equipped in terms of number of staff and specific MedTech expertise beyond REACH to fulfil its increasing new tasks (e.g., under RoHS but also Batteries Regulation, ESPR or OSOA common chemicals platform).

Law: Stockholm Convention on Persistent Organic Pollutants and Regulation (EU) 2019/1021 (POPs)

Issues triggering administrative burden:

- Tracking implementation in all the parties is complex, as the implementation is not homogeneous.
- Lack of medical device/IVD specific considerations and workable transitional arrangements from the beginning.
- Substances added to the Stockholm Convention may cause sudden supply chain disruptions as global suppliers may halt production or discontinue materials. Notification requirements can make suppliers cautious or non-cooperative.
- Regulatory misalignment between POPs decisions taken at the international level and their implementation in the EU, including regulatory misalignment between POPs legislation and MDR in terms of risk-benefit justifications, substance-specific derogation timelines and definitions (e.g.

"use" vs "intentionally added"). This may cause increased complexity for global product stewardship and regulatory teams. • Lack of analytical and substitution support: Devices often contain complex materials and coatings in small quantities, making detection, quantification, and substitution of POPs difficult. There is limited availability of validated analytical methods for trace POP detection. This increases testing cost and increases risk of non-compliance due to analytical uncertainty.
Possible solutions: • A reinforced stakeholder consultation mechanism ahead of COP meetings on envisaged substance listings and required transitional arrangements for MedTech • Implement MedTech specific Stockholm Convention requirements consistently at EU level, especially introduce transition periods and phased implementation for redesign and substitution, allowing time for validation and regulatory approval. • Promote inter-regulatory coordination to ensure POPs restrictions are risk-proportionate and compatible with medical device lifecycle and safety standards; align on appropriate safe levels for human health and environmental compliance. • Align derogations and exemptions with MDR/IVDR provisions on essential performance and safety requirements to ensure patient protection remains the priority.

Law: Regulation (EC) No 1272/2008 – CLP (Classification, Labelling and Packaging of Substances and Mixtures)
Issues triggering administrative burden: • Medical device manufacturers may be indirectly impacted by CLP obligations when handling classified substances or mixtures used in manufacturing, sterilisation, or maintenance (e.g. adhesives, coatings, cleaning agents). • Overlap with REACH and MDR creates uncertainty regarding classification responsibilities, especially for borderline products or substances used in device components. • Frequent updates to hazard classes and labelling rules (e.g. new endocrine disruptor or PBT categories) increase the complexity of compliance and may require reclassification of materials already assessed under MDR. • Inclusion of additional hazard classes (endocrine disruptors, PBTs, vPvBs, PMTs, vPvMs) in CLP represents a departure from the Globally Harmonized System, risking fragmentation of an essential component of international chemical management. • IVD manufacturers as formulators of mixtures are also directly impacted by CLP. In addition, hazards assessments and CLP-labelling requirements are incorporated in IVDR itself, and not all IVD (and MD) uses are covered under the CLP scope exemption of Article 1(5)(d).
Possible solutions: • Provide clear guidance on the applicability of CLP to IVDs that are formulated mixtures. Medical devices, especially for substances used in manufacturing but not present in the final product. • Promote regulatory coherence between CLP, REACH, and MDR/IVDR, including mutual recognition of hazard assessments and labelling exemptions for MDR/IVDR-compliant devices. • Allow simplified or sector-specific labelling provisions for substances used exclusively in controlled healthcare or industrial settings.

Law: Directive 2011/65/EU – RoHS (Restriction of Hazardous Substances in EEE)
Issues triggering administrative burden: • Legal uncertainty and inconsistencies:

  - The parallel application of RoHS, REACH and MDR/IVDR creates ambiguity and duplicates compliance efforts for medical technology manufacturers, particularly regarding substance restrictions and documentation.
  - RoHS validity periods do not reflect practical realities (i.e., timelines required for redesign testing, MDR/IVDR regulatory approval)
  - RoHS exemption renewal process is slow and unpredictable, risking supply chain disruptions and potential discontinuation of essential medical technologies that rely on specific materials.
- Proportionality of RoHS restrictions on MedTech: The RINA cost-benefit analysis submitted with the 2022 Call for Evidence found that medical technology companies invest a disproportionate level of product engineering resources to continuously assess new and existing designs, to account for numerous amendments to RoHS Annex III & IV, with a limited reduction in RoHS substances and associated emissions at end of life.
- Impacts on patient access to MedTech: Restrictions on materials may outpace innovation, limiting the availability of validated alternatives suitable for medical use and potentially delaying patient access to critical technologies.
- The amendments to EN IEC 63000:2018 proposed in the European Commission's most recent draft standardisation request are deviating from the risk-based approach underlying the current standard and the RoHS directive. The principle of 'self-declaration' for CE conformity under the RoHS Directive is long standing and there is no clear evidence that this should be revoked.
  By requiring mandatory test reports, the proposed amendments seemingly conflict with the European Commission's renewed emphasis on "minimising administrative burdens and streamlining implementation". Managing test reports on the level of several thousands of homogeneous materials in parts will lead to significant, disproportionate costs for EEE manufacturers and their suppliers.
  The current standard already includes provisions on identifying any exemptions applied to parts/components as well as the requirement to do analytical testing where there is a high, unmitigated risk of hazardous substances being present.

Possible solutions:

- Exempt existing (already MDR/IVDR approved) medical equipment from future RoHS changes (substance restrictions and exemption requests)
- Grant category 8 medical devices and in vitro diagnostic medical devices longer transition and validity periods
  - Transition periods that are minimum three years later compared to other EEE (for *denied exemptions*)
  - New substance restrictions that foresee a transition period of at least seven years (as was done with RoHS 1)
  - Validity periods for exemptions (*renewed*) of at least 10 years
- Establish a default exemption for recovered parts
- Consider the global proliferation of RoHS when making changes
- Ensure all relevant stakeholders are consulted throughout the decision-making process
- Update the definition of "Active Implantable Medical Devices", RoHS Article 2(4)(h)
- Transform RoHS into a Regulation
- Keep RoHS & REACH separate
- Support transitional measures and targeted R&D incentives to accelerate the development and validation of compliant materials for medical use
- Ensure that the EU Chemicals Agency (ECHA) is adequately equipped in terms of number of staff and specific MedTech expertise beyond REACH to fulfil its new RoHS tasks following the OSOA package reform
- Maintain RoHS standard EN IEC 63000:2018 (no requirement of mandatory test reports)

Law: Regulation (EU) 528/2012 – Biocidal Products Regulation (BPR)
Issues triggering administrative burden: • Disinfectants, preservatives, and antimicrobial coatings used in or on medical devices may fall under BPR, even when the device is already regulated under MDR, creating dual compliance obligations. • Complex regulatory interface between BPR and MDR leads to legal uncertainty, especially regarding treated articles and borderline products (e.g., EtO or ethanol). • Lengthy and unpredictable active substance approval timelines can delay market access or disrupt continuity of supply for essential healthcare products.
Possible solutions: • Establish a clear and coordinated interface between BPR and MDR, including guidance on treated articles and borderline cases. • Enable mutual recognition or cross-referencing of assessments conducted under MDR (e.g. for safety, efficacy, and risk management) to streamline compliance. • Introduce fast-track or priority procedures for biocidal substances used in critical healthcare applications, ensuring continuity of patient care.

4. Conclusions

The medical technology sector is a densely regulated sector (see Annex 1 overview slide of the MedTech specific regulatory ecosystem). Simplification of EU environmental regulation should be an opportunity to align EU environment legislation with the sector specific legislation established through Regulations (EU) 2017/745 and 2017/746. In particular:

- Environmental compliance deadlines, for reporting and/or material requirements should allow for sufficient transition times taking into account the regulatory approval process timelines as outlined in the annex.
- Digital compliance tools should replace paper-based tools.
- The “One environmental parameter-one reporting” principle should be introduced.
- Definitions should be aligned across environmental regulations taking the NLF as a blueprint.
- Fragmentation of requirements across Member States should be combatted and an EU-level one-stop-shop EPR reporting gateway for registration and reporting should replace national regimes.

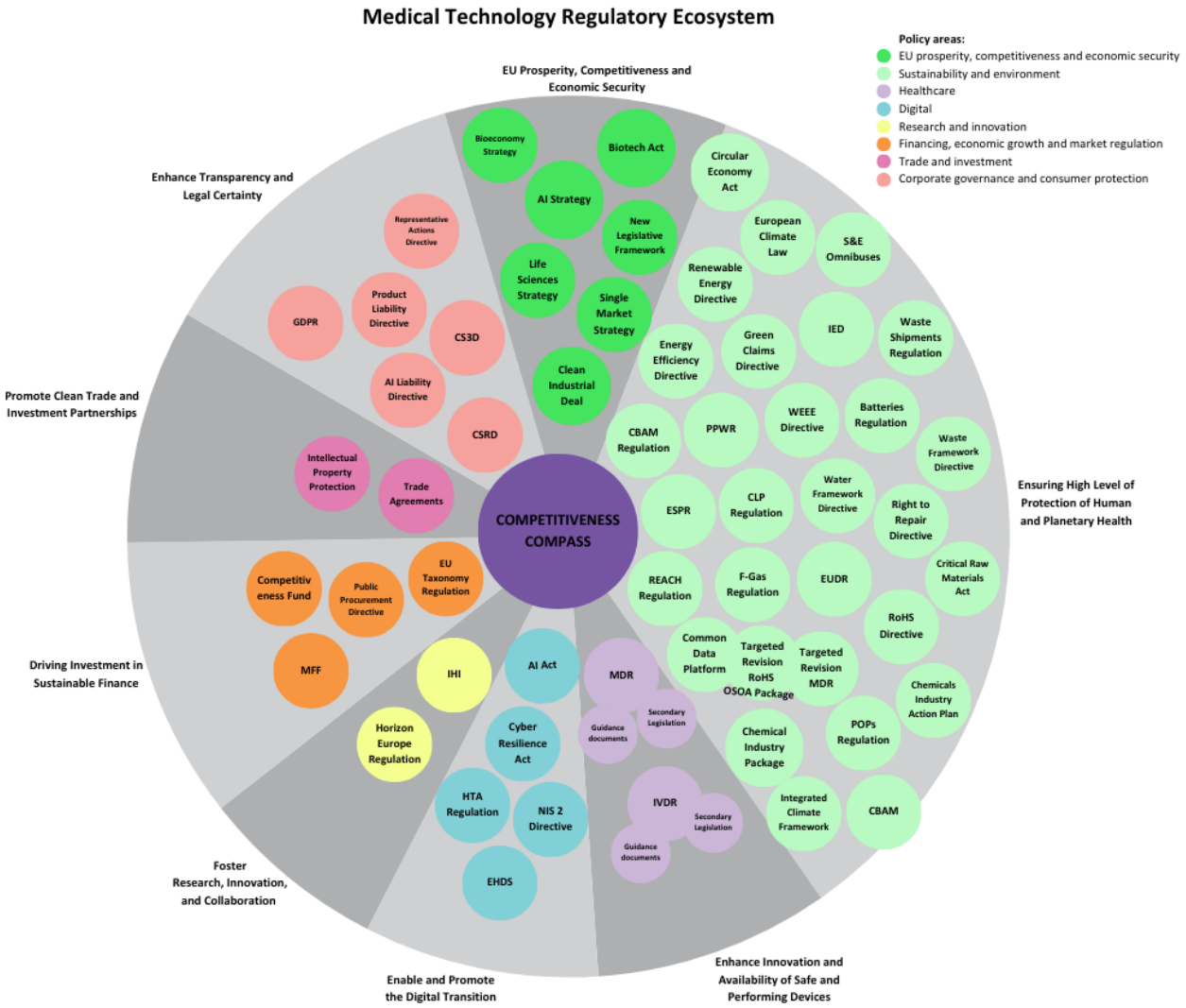
5. Supporting evidence

We submit the following substantiating evidence to the European Commission’s call for evidence:

- MedTech Europe report commissioned to BCG on “Decarbonising healthcare: how a competitive medical technology industry can contribute”, June 2025
- EU Prosperity and Competitiveness: recommendations for implementing the EU Green Deal in healthcare - MedTech Europe
- Priorities for the EU Clean Industrial Deal – MedTech Europe
- Priorities for the EU Circular Economy Act - MedTech Europe
- Priorities for the EU Chemical Industry Package - MedTech Europe
- MedTech Europe Position – Reinforcing the EU Single Market for Innovation, Health Resilience and Competitiveness, April 2025
- MedTech Europe response to EC call for evidence on revision of the New Legislative Framework, September 2025

- MedTech Europe position on OSOA package, February 2024
- Joint industry statement on harmonised Waste Sorting Instructions for packaging,, July 2025
- MedTech Europe Response to EC WEEE Review Consultation 2023
- RINA RoHS Socioeconomic Impact Assessment Study (2022)
- MedTech Europe - Position Paper on RoHS review (2022)
- MedTech Europe response to EC call for evidence on Integrated Climate Resilience and Risk Preparedness Framework, September 2025
- MedTech Europe recommendations on EU Life Sciences Strategy, April 2025
- MedTech Europe response to Call for Evidence on EU Stockpiling, May 2025
- MedTech Europe response to EC consultation on Strategy to Support Medical Countermeasures against Public Health Threats, May 2025
- EU Competitiveness Compass, January 2025
- EU Life Sciences Strategy 2025
- EU Preparedness Union Strategy, March 2025

Annex 1: Overview of the regulatory landscape for the European Medical Technology Sector



Annex 2: Overview of the design cycle steps required for a medical technology

High-level required steps:

Step 1: Generic testing

Finding an alternative, that performs as well as or better than the former substance/material/technology:

- Changing to an alternative material must follow medical device regulations
- Evaluate feasibility for alternate options, product development, verification/validation, aging testing, biocompatibility testing, pre-clinical studies, clinical trial, and regulatory submissions and approvals
- 10+ years to redesign per impacted product; multiple product changes will result in longer timelines from testing to selecting an alternative (see below for detailed steps)

Step 2: Specific device testing (indicative best-case timings)

- Material feasibility testing (incl. pre-clinical, animal safety testing and design verification) – at least 1 year
- Sample testing / making parts for testing, including industrialisation / Change of manufacturing processes and tools – at least 1 year
- Formal Verification & Validation (V&V) testing – at least 1 year
- Biocompatibility testing – at least 6 months up to 2 years dependent on the device type
- Clinical phase submissions/approvals – at least 6 months
- Clinical trial enrolment – at least 2.5 years
- Clinical trial follow-up – at least 1 year
- Clinical trial report – at least 3 months
- Quality Lab
- Regulatory submissions – at least 1 year
- CE regulatory approval – at least 18-24 months; 5-26 months if for the rest of the world (regulatory approval timing assumes regulatory bodies could support these product submissions *without delays*)
- Procurement time – at least 1-3+ years[6]

High-level required steps	Exemplary process steps required depending on scope of individual materials require replacement
Identify potential materials and supplier for alternatives	Evaluate new material(s) based on: - Material properties (e.g., electrical resistivity, tensile strength, durability, chemical resistance, temperature resistance, biocompatibility, etc.) - Intended use/function of material (one alternative may not be suitable for all application) Evaluate Suppliers: - Supplier capabilities & costs - Suppliers Quality Management Systems (QMS) & Documentation to ensure traceability - System integration feasibility in Entreprise Resource Planning (ERP) system for data exchange

[6] This could be highly variable, depending on the Technology Readiness Level of the material, which is especially relevant if a new substance has to be invented to replace the given PFAS. For example, if the new substance has only been synthesized at lab-scale, then the upstream supplier may spend years on scale-up, to make the substance available at a commercial production scale. Ideally, an alternative could be identified which is already available commercially, butthis cannot be ensured for PFAS, and all uses.

Define/Select potential alternative(s) material/supplier and frame project	- Select material or multiple alternatives by balancing risks on costs and timeline for testing
	- Establish project plan & test plan to define resources to introduce alternative material
	- Secure project funding & resources for material testing & implementation:
	  ○ Management buys in for decision (constraints depending on financial capabilities and availability of resources)
	  ○ Technical project lead
	  ○ Supplier (capability to provide sample for testing)
	  ○ R&D (evaluate risks for contamination and/or suitability of material used)
	  ○ Manufacturing for functional testing
	  ○ Regulatory for impact on global registrations
	- Initiate change control process and collect stakeholder inputs:
	  ○ Evaluate Regulatory constraints
	  ○ R&D
	  ▪ Evaluate scope & documents required update due to material change (risk management)
	  ▪ Define test lab
	  ▪ Initiate risk assessment for new material Design Failure Mode and Effect Analysis (DFMEA)/ Process failure mode and effects analysis (PFMEA)
	  ○ Manufacturing
	  ▪ Evaluate risks and establish conditions for functional testing to evaluate alternatives without impacting regular production (risk for contamination and other control measures required for test execution)
	  ○ Procurements & Software Quality Assurance (SQA)
	  ▪ Setup new supplier

Test alternative(s)	- Produce parts for testing - Prepare test setup - Identify Quality lab and contract new lab if required (NDA where required) - Formal V&V process: Execute testing and evaluate manufacturing process capabilities - If required, return manufacturing condition to regular production after functional & V&V testing until test outcome (>3 month lead time if Biocomp and Packaging Tests are additionally required to simulate material stability and behavior on long term performance). - Biocompatibility tests including extractable and leachable test
Select & Implement alternative	Execute Change Control Process - Approve alternative material

	- Approve and implement new supplier (agree on contract and condition) - Update technical documentation (drawing, DMFEA/PFMEA, technical summary files, IFU, labeling, material specification, etc.) - Update of manufacturing procedures & process (Design transfer), if needed update or source/setup production equipment - Update IFU & Labeling update or register new product - Regulatory product registration if required (510k, CE and others where required) - Initial sample testing - Market release (Customer training, Marketing campaign etc.) - Compliance assessment of new material and local requirements for substances

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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