MedTech Europe's Key Recommendations for the Revision of Directive 2012/19/EU on Waste of Electrical and Electronic Equipment

Brussels, 5 November 2025

Introduction

MedTech Europe – the European trade association for the medical technology industry, including diagnostics, medical devices, and digital health – acknowledges the importance of the Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU, and the role it has had in efficiently managing the generation of WEEE. It also appreciates that it has been crucial in the reduction of negative impacts on the environment and on human health, and in retrieving/recycling of secondary raw materials from WEEE.

MedTech Europe welcomes the European Commission's stakeholder consultation on the upcoming Circular Economy Act as an opportunity to discuss the upcoming revision of the WEEE Directive. It aims at providing feedback and recommendations from the perspective of the medical technology sector with the implementation of the Directive, its benefits, key challenges and opportunities.

Manufacturers of medical technologies are committed to continuously improving the environmental performance of their processes and products. MedTech Europe recognises the improvements and milestones that have already been achieved in the last decade, with the share of reported collected WEEE classified as 'medical devices' (which according to the WEEE Directive also includes *in vitro* diagnostics) almost doubling from 2012 to 2017[1].

The medical technology industry shares the objectives of the Directive to contribute to sustainable production and consumption by:

- Contributing to the efficient use of resources and the retrieval of secondary raw materials through re-use, recycling and other forms of recovery,
- Improving the environmental performance of all actors involved in the life cycle of electrical and electronic equipment (EEE), and
- Preventing the creation of WEEE as a priority.

To that end, this paper focuses on, and provides sector specific recommendations to, the following points:

- The scope of the WEEE Directive
- Regulatory coherence between the WEEE Directive and the sector specific Medical Devices Regulation and the *In Vitro* Diagnostic Medical Devices Regulation
- Seeking better harmonisation of WEEE Management

[1] Study supporting the evaluation of the WEEE Directive, 2025, p. 87

1. Scope

The WEEE Directive currently contains certain concepts that are either not defined, differently interpreted at national level or not in line with the New Legislative Framework and related sectorial legislation (on medical devices and *in* vitro diagnostics, please see the following chapter), resulting in varying requirements and legal uncertainty.

This has been best demonstrated by the six infringement procedures undertaken by the Commission against Member States (Estonia, Ireland, Austria, Czechia, Sweden and Romania[2]) following conformity assessment studies that demonstrated transposition gaps of the Directive. In particular, MedTech Europe stresses that out of all the infringement cases, three (Estonia, Austria and Romania) were partially due to the terminology of 'medical devices' and 'in vitro diagnostic medical devices' not being transposed into national legislation.

The incomplete transposition of the WEEE Directive at national level, in particular with reference to medical technology, has created uncertainties for producers, producer responsibility organisations (PROs) and waste management operators. Additionally, it has created an unequal level playing field for the collection and reporting of WEEE depending on which national legislation is applicable.

Additionally, a more comprehensive set of definitions is necessary to allow for a clearer and more cohesive transposition of the Directive. Examples of definitions that are needed are for the terminology of 'electronic device' and 'spare and service parts'. Currently the WEEE Directive provides no such definitions.

Lastly, MedTech Europe underlines the relevance of the Article 2(4)(g) scope exclusion for medical devices and *in vitro* diagnostic medical devices, where such devices are expected to be infective prior to end of life and for active implantable medical devices. The exemption is crucial to guarantee human and planetary health, as it ensures that contaminated WEEE in the healthcare context does not end up infecting other WEEE streams or waste handlers. This supports the safe management of waste and promotes a healthy circular economy process, whilst curbing the amount of contamination. As long as remaining circular economy barriers, such as regarding waste shipment, are not removed, the relevance of this scope exclusion persists.

MedTech Europe Recommendations:

- **Maintain the current scope of the WEEE Directive** which covers all finished EEE unless explicitly exempted and excluding non-finished EEE, such as spare parts, from the scope.
- Maintain the current **Article 2(4)(g) exemption** for "*medical devices and in vitro diagnostic medical devices where such devices are expected to be infective prior to end of life, and active implantable medical devices*".
- While national (regulatory and waste management) barriers to effective collection and recycling of **infected medical devices** persist across Member States, they should remain outside of the scope of the WEEE legislation. However, a **thorough analysis and review of national/regional/local provisions related to infected healthcare waste** is proposed, as well as **increased investment in collection and recycling infrastructures at healthcare facilities.**
- **Align the definitions of "manufacturer" and "placing on the market" with the New Legislative Framework and associated Blue Guide** which is also the foundation for further MedTech relevant product legislation (e.g. MDR & IVDR, Radio Equipment Directive, Artificial Intelligence Act).

[2] Commission Staff Working Document on the Evaluation of the WEEE Directive, 2025

- **Clear and harmonised definitions of all economic operator roles**, including of "producer" should be in line and coherent across all the EPR legislations (e.g. Batteries and Waste Batteries Regulation & Packaging and Packaging Waste Regulation).
- **Additional guidance at European level to harmonise the interpretation of "EEE" and the reporting categories** to ensure a harmonised scope application across the EU
- **Introduce a "one stop shop digital EPR gateway at EU level" for EPR registration and reporting**

2. Regulatory Coherence

Overlaps and inconsistencies with environmental legislation

There has been a considerable increase in the overlaps and inconsistencies between EU product, waste and chemical legislation since the last revision of the WEEE Directive. This has led to an increase in complexity in dealing with WEEE across Europe and in dealing with the WEEE Directive alongside other Green Deal legislation such as, but not limited to.,

- Regulation (EU) 2024/1781 on Ecodesign of Sustainable Products
- Regulation (EU) 2023/1542 on Batteries and Waste Batteries
- Regulation (EU) 2025/40 on Packaging and Packaging Waste

From a product legislation perspective, the newly published Ecodesign for Sustainable Products Regulation (ESPR) provides a particularly comprehensive framework for regulating the design of products. Consequently, product related provisions of the WEEE Directive should be removed to avoid unnecessary legislative overlap. For example, requirements related to recyclability or recycled content, should be developed under the ESPR, taking into account specific safety and performance requirements under the Medical Devices Regulation.

Overlaps and inconsistencies with sectoral legislation

In addition to other environmental legislation, MedTech Europe stresses the need to ensure alignment between the WEEE Directive and the sector specific regulatory framework. This means that the Revision of the WEEE Directive should reflect the unique specificities of the medical technology sector, as outlined by the by the Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). This would allow for good harmonisation between the environmental and sustainability goals of the WEEE Directive while ensuring that the safety, integrity, and security of supply of medical technologies are respected.

A clear example of the need for more alignment between the revision of the WEEE Directive and the medical technology regulatory landscape would be the inconsistency in terminology of 'medical devices' in Annex IV. This is because Annex IV lays down a "non-exhaustive list of EEE which falls within the categories listed in Annex III", and divides it in temperature exchange equipment, screens and monitors, lamps, large equipment, small equipment, and small IT and telecommunications equipment.

Within Annex IV, medical devices are divided into 'large medical devices' and 'small medical devices', which are set as subcategories of both 'large equipment' and 'small equipment', respectively. However, the terminology 'large medical device' and 'small medical device' are inexistant in the MDR. Medtech Europe then suggests clearly defining such devices in the upcoming revision, using a clear criterion.

Additionally, there also is need for more alignment between the WEEE Directive and the medical technology sector specific legislation with regards to the terminology of 'active implantable medical devices' (AIMD). Currently, Article 3(1)(o) of the WEEE Directive defines AIMD as "*within the meaning of point (c) of Article*

1(2) of Council Directive 90/385/EEC". Nevertheless, this wording is outdated, as Directive 90/385/EEC was repealed on 26 May 2021 and was replaced by Regulation (EU) 2017/745 on Medical Devices, which does not clearly define AIMD. A new definition is then suggested in the recommendations below.

MedTech Europe Recommendations:

- **Remove from the WEEE Directive Article 4 on product design and Article 14 on information for users** as product related aspects are more comprehensively covered by the ESPR.
- Ensure that the revision of the WEEE Directive will be coherent with other applicable EPR Regulations, namely, **Regulation 2023/154 on Batteries and Waste Batteries** and **Regulation 2025/40 on Packaging and Packaging Waste Regulation**
- The definition of *active implantable medical devices (AIMD)* needs clarification. MedTech Europe recommends the following wording adjustment: "*active implantable medical device' means any active implantable medical device or system within the meaning of point (c) of Article 1(2) of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices or any medical device within the meaning of both Article 2(4) and Article 2(5) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC"*.
- Clarify in the legal text the wording of **'large medical devices' and 'small medical devices'** in Annex IV when classifying types of EEE.

3. Better Harmonisation of WEEE Management

There currently are considerable limitations in the application of the WEEE Directive in the form of divergent national registration and reporting requirements, as they diverge significantly across the Member States. Harmonisation across the entire European Union, through consistence enforcement and implementation, is of the utmost importance. For instance, a medical device producer may need to register separately in each Member State, with different reporting formats and timelines. This leads to fragmented compliance systems that absorb significant administrative resources, especially for SMEs, and can delay product availability across borders.

The registration process in each EU Member State has particularities among which are data requirements and responsibility burdens. A specific burden is showcased by the different signature acceptance, whereby in some Member States, digital signature accepted, while in others, only a 'wet' signature is the accepted protocol by the national registry authorities. A clear example is Germany, which strictly imposes and requires a 'wet' signature from company authorised signatory during the registration process.

Additional fragmentation is seen as in some Member States, such as Denmark, where only authorised persons with personal (or company) MitID can register the sales or obligated party/entity with the DPA. That poses administrative challenges and impacts the functioning of the single market. Another example is Ireland, where the WEEE scheme requires the local entity of a company to be the working office, identifiable with a staff presence.

Reporting data to compliance schemes has proven to be at times, equally burdensome and confusing due to the multiple differences in the required information, often in local language, by each compliance scheme in part. The requested info differs from simply the quantity of the device/product to the chemistry*of batteries

or product. The reporting complexity is particularly evident for WEEE in France with ESR and WEEE in Austria with ARAPlus.

A better harmonisation of EU reporting standards is necessary to create and maintain a robust WEEE reporting process. Online registers have limitations and would benefit from improved usability, and currently only France, Germany, Italy, the Netherlands, Slovakia, Spain and Denmark, provide or enable access and overview of their EPR public registers.

In the interest of a better harmonised level playing field with respect to the treatment of WEEE, MedTech Europe supports the adoption of EU wide harmonised standards laying down minimum common treatment conditions. The Commission should use the given mandate for a Delegated Act set in Article 10(3) of the WEEE Directive.

MedTech Europe Recommendations:

- **Turn the WEEE Directive into a WEEE Regulation** aiming to better harmonise implementation across the EU.
- **Require all actors handling WEEE to register and report quantities through a unified system at EU level**
- Enact a WEEE Regulation with **clear definitions** which should require **reporting obligations within same timeframes and formats.** That includes a harmonised methodology for calculation of EPR fees and a single point of access to all EPR schemes. We call for introducing **a "one stop shop digital EPR gateway at EU level" for EPR registration and reporting**
- Mind caution before advancing further labelling requirements at national level, **better harmonise current labelling fragmentation in requirements for size, visibility, and placement of the crossed-out wheeled-bin symbol.**
- Digitise marking through the **use of a data carrier solution on the packaging**, such as a QR code.
- Promote the **mandatory use of EN 50625 standards** in all EU Member States.
- **Continue to use standard EN 50419** on marking of electrical and electronic equipment (EEE) in respect to separate collection of WEEE, to ensure a smooth revision.
- **Eco-modulation, if implemented, should be harmonised across EU member states**, and **focus on elements relevant to the objectives of the legislation**.
- **Better harmonise the calculation method of the WEEE collection rate**

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 that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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