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Position Paper: **The "Opt-In" Provision of the EU MDR (Article 17):**

- **Undermines EU Law and the Single Market**
- **Deprives Hospitals of Sustainable Medical Device Options, and**
- **Exacerbates Shortages in the Healthcare Supply Chain**

The time has come to change it.

January 2024

Summary

Health systems are under enormous pressure. Urgently needed amendments to Article 17 of the EU Medical Device Regulation (MDR) would help:

- Alleviate supply chain disruptions – these were laid bare during the pandemic and remain critical for some medical devices;
- Reduce the surprisingly high environmental toll and costs generated by healthcare;
- Promote more innovative and competitive medical devices;
- Advance the Commission's and Parliament's desire to remove EU regulatory barriers that impede circular economy solutions, such as device remanufacturing; and
- Address changed political circumstances since the original passage of the EU MDR.

The Association of Medical Device Reprocessors (AMDR), the trade association representing regulated, commercial medical device reprocessing and remanufacturing[1] companies urges Article 17 be amended to:

- Remove the illegal regulatory barrier (portion of 17.1) restricting the sale of CE-marked remanufactured devices on the whole of Europe to state: "17.1 Reprocessing and further use of single-use devices may only take place ~~where permitted by national law and only~~ in accordance with this Article;"
- Amend Art. 17.3 to instruct the Commission to provide guidance back to Member States on their requirements in overseeing Common Specification (CS) reprocessing by

[1] "Reprocessing" is the regulatory term; though, in Europe, "remanufacturing" has been adopted by some authorities, notified bodies and reprocessors to refer to commercial, MDR compliant and, thus, CE-marked reprocessing of single-use devices (SUDs).

hospitals and third parties, to ensure that Member States that allow CS reprocessing must also allow CE reprocessing.

- In the absence of any Notified Bodies willing to certify 17.5 described reprocessing, we propose to amend the section to require hospitals or commercial reprocessors seeking to reprocess according to the Common Specifications, to be required to demonstrate conformance with the internationally accepted standards: ISO 13485 Quality Management Systems, ISO 14971 on Risk Management, ISO 60601 on Medical Electrical Equipment and ISO 10993 on Biocompatibility.
- Remove the needless and restrictive 17.6 provision; and
- Remove the regulatory barrier (17.9) that allows Member States to impose, without medical or scientific justification, a higher standard for reprocessed devices than for any other medical device.

Rationale:

1. **Article 17 conflicts with the larger harmonization objective of the Medical Device Regulation.** Reprocessing was one of the final subjects to be decided in the MDR. Unable to reach a consensus, Parliament ultimately passed a complicated range of options in the EU MDR that gives Member States the option to (a) "opt-in" to allow reprocessing compliant with EU MDR requirements, (b) do nothing, thereby, disallowing it entirely, or (c) allow hospitals to reprocess according to Common Specifications. This "a la cart" menu for reprocessing runs counter to the objective of the EU MDR, which is to harmonize requirements across the EU.
2. **CE marked devices, by definition, conform to the MDR's health and safety requirements.**
   Article 17.1, allows Member States to restrict the sale of CE-marked, remanufactured devices in their territories. This is a violation of both the Treaty on the Functioning of the European Union and the principle of free movement of goods. This breach also undermines the meaning behind the CE mark itself, which demonstrates that a product complies with directives. *We find no other example of any other product where Member States are allowed to prospectively prohibit sales of CE-marked products.* Article 17.6 similarly allows only devices previously placed on the market to be reprocessed, despite the reprocessed version having obtained its own CE mark. This is bad public policy and opens the door to further erosion of the credibility of the CE mark, the Treaty, and the free movement of goods.
3. **Medical device remanufacturing is an immediately available circular economy solution.** Parliament is intent on removing regulatory barriers to attain a circular

economy. Article 17's "opt in" and 17.6 provisions are a barrier to both an innovative, circular economy solution and the free movement of goods. In the case of CE-marked, remanufactured SUDs, the EU MDR allows Member States to prohibit the use of a readily available solution that reduces costs, waste, and emissions while building supply chain resilience.

4. **Member States that elect Common Specification reprocessing can't comply with the Regulation.** Some Member States are also electing to allow reprocessing in compliance with the EU Commission's delegated act, the Common Specifications under 17.3/17.4. This cannot be implemented as no Notified Body for certifying conformance to the Common Specifications is available in Europe, as required in 17.5.
5. **The political situation has changed.** Even Member States initially opposed to reprocessing now support it. France, Germany and Spain (in addition to strong support in the UK), have either initiated demonstration projects or allow SUD remanufacturing. Six Members States already have opted in. Additional pressures since COVID underscore the need to improve supply chains and reduce emissions and waste, and they are further driving Member States to allow EU MDR-compliant remanufactured devices.
6. **The EU lags behind other first world nations in the remanufacturing of medical devices.** In a twist to the common notion that the EU is far ahead of the rest of the world in addressing sustainability, fewer than 1,000 hospitals in Europe mainly in Germany have regulated, commercial remanufacturing programs while more than 9,000 hospitals and surgical centers have such programs in the US and Canada. This is giving America a competitive advantage over Europe in the promotion of a green, innovative industry that cuts cost, waste and emissions, and builds resilience in the supply chain. Even Japan allows regulated remanufacturing on the entirety of their market.