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Position Paper:

Supporting the European Commission's Proposed Amendments to Article 17 of the EU MDR

Parliament and the Council Can Advance Strong and Sustainable Healthcare

The Association of Medical Device Reprocessors (AMDR) welcomes the European Commission's proposed reforms to Articles 17 and 61 of the EU Medical Device Regulation (MDR). If adopted by the European Parliament and Council, the Commission's proposal will:

- **Restore the EU's Single Market and harmonized regulatory principles** with respect to "single-use" medical devices (SUDs).
- **Align the EU MDR with proven frameworks** that have succeeded in other jurisdictions for decades.
- **Encourage greater adoption of reprocessed and fully refurbished devices**, which enhance the circularity, affordability, and resilience of healthcare.
- **Put in place stringent, but reasonable and pro-competitive** clinical evaluation procedures.

However, AMDR urges Parliament and the Council to make one amendment to the proposal:

- **Explicitly preserve the Common Specifications (CS) pathway** for SUD reprocessing, provided that the reprocessing complies with CS adopted by the Commission, compliance is certified by a notified body, and the reprocessed device is not being "placed on the market" (e.g., where it remains the property of the hospital and is being serviced by a third-party).

  This successful service-based model must not be inadvertently eliminated. Under the current EU MDR, many member states have adopted and relied on this regulatory pathway, and the Commission has already adopted extensive CS (2020/1207) as a delegated act. AMDR seeks to maintain that established circular strategy.

AMDR supports the adoption and implementation of this proposal—with this targeted amendment—so that the EU may enjoy the benefits of reprocessed and refurbished SUDs and align with the stated desires of its clinicians and clinical societies.

> ***Note on terminology:*** *In EU regulatory terms, "reprocessing" does not refer exclusively to regulated SUD reprocessing, but also to in-house sterilization of reusable devices in hospitals. Currently, Notified Bodies often describe regulated SUD reprocessing as "remanufacturing," while the proposed reforms would use the term "full refurbishing." Please see AMDR's glossary of terms for more information.*

Preserving the Single Market and the EU's Regulatory Authority

Under the current MDR, Article 17 introduces an "opt-in" system that allows Member States to ban or restrict the use of CE-marked fully refurbished SUDs within their territories. As AMDR has documented, this approach undermines regulatory harmonization and creates a *de facto* trade barrier—exactly what CE marking and the EU Single Market is supposed to prevent.

In its study on the implementation of Article 17 in the EU medical devices market, the Commission addressed the shortcomings of this framework:

"The current regulatory framework seems to be…leading to potential confusion and dissatisfaction among stakeholders. [Healthcare institutions and manufacturers] reported a lack of interest in reprocessing due to the diversity and complexity in the national implementations of the regulations in various Member States, in other words, the lack of a common EU-wide approach."

In addition to undermining a circular industry, regulatory fragmentation threatens the integrity of the CE mark and the regulatory authority of the EU itself. For a product to receive a CE mark, it must meet stringent, evidence-based, safety and performance standards. To allow Member State officials to override that judgment in the case of fully refurbished SUDs contradicts EU principles of unified law.

The Commission's proposal omits the "opt-in" provision, or any other national-level gatekeeping mechanism, and replaces it with a unified, EU-wide framework—thereby upholding the regulatory and market integration on which the EU was founded.

Full Refurbishers-as-Manufacturers—A Proven Model

Article 17(3) of the Commission's proposal returns fully regulated SUD reprocessing to the established concept of "full refurbishing," and appropriately treats any entity that carries out such refurbishing as manufacturers. This will entail holding full refurbishers to equivalent safety and performance standards as original manufacturers.

AMDR agrees that entities carrying out full refurbishing and placing devices on the market should be regulated as manufacturers. The MDR would thus align with similar regulatory frameworks that have preserved patient safety for more than 25 years around the world—and keep all pathways for selling CE-marked devices clear, consistent, and accountable.

Supporting Safe Reuse and Sustainability

AMDR also endorses the proposed Articles 17(1) and 17(2), which require manufacturers to justify SUD labeling and to provide reprocessing instructions for reusable devices. These measures, collectively, will encourage safe reuse, reduce unnecessary waste, and align with broader EU objectives on sustainability and the establishment of a circular economy. This is particularly urgent given ongoing planetary, epidemiological, trade, and geopolitical pressures.

AMDR's Requested Amendment: Preserve Common Specifications

The CS pathway—built largely on a long-established regulatory framework that existed in Germany—has effectively ensured safe, regulated reprocessing for years. Many member states have elected to regulate reprocessing under the delegated act CS pathway. AMDR strongly supports preserving this model for the reprocessing of SUDs wherein it complies with CS and is certified by a notified body.

As currently drafted, however, the Commission's proposal only addresses the "placing on the market" of fully refurbished SUDs. But CS reprocessing includes service-based models in which SUDs are not "placed on the market," such as third-party reprocessors acting on behalf of hospitals in servicing hospital owned equipment.

AMDR encourages Parliament and the Council to explicitly address this in the legislative text by adding a new **Article 17(5)**. The text should clarify that SUD reprocessing shall be permitted under CS provided that the reprocessing complies with the CS already adopted by the Commission (Implementing Regulation 2020/1207 of 19 August 2020) and is certified by a notified body.

This approach would preserve the long-standing distinction between (1) full refurbishing for market placement and (2) CS-based SUD reprocessing carried out as a service for a health institution. That distinction is not a relaxation of safety standards. On the contrary, it preserves a proven, highly regulated pathway that enables safe reprocessing while avoiding the unnecessary elimination of an important circular-economy model currently relied upon by European hospitals.

Requested Legislative Amendment

AMDR encourages the Parliament and Council to adopt the following new **Article 17(5)**:

5. By way of derogation from paragraph 1 of this Article, the reprocessing of single-use devices according to common specifications may continue to be permitted provided that the following cumulative conditions are met:

- ***(a)** the reprocessing is performed in accordance with the common specifications published in Implementing Regulation (EU) 2020/1207 of 19 August 2020; and*
- ***(b)** compliance of the reprocessing with the common specifications is certified by a notified body.*

Conclusion

AMDR believes the Commission's proposed replacement of Article 17 delivers balanced and precedented solutions in key respects. The new Article 17 would restore the integrity of the Single Market and the authority of the CE mark, align with proven regulatory models, and encourage circular economy practices without weakening MDR standards.

At the same time, the final text should be amended to preserve and clarify the CS pathway for SUD reprocessing, provided the reprocessing complies with CS adopted by the Commission by delegated act and is certified by a notified body.

We therefore urge the European Parliament and the Council to adopt the Commission's proposal, with a targeted amendment to preserve successful CS pathways, so that the EU can preserve and strengthen effective, safe, and sustainable pathways for the reprocessing and full refurbishing of SUDs.