

**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.**

March 2025

**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<sup>1</sup> 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

---

<sup>1</sup> “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, and to ensure that Member States that allow CS reprocessing must also allow CE reprocessing.

- Urge Notified Bodies to certify CS reprocessing given there are no such NBs as of yet.
- 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 must ensure it is compliant with 17.5.** 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. Any purported CS reprocessing taking place must be accredited by an Notified Body to ensure patient safety. The Commission should advise member states and take enforcement action if necessary. The Commission should also urge Notified Bodies to certify CS reprocessing
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. 11 EU Member 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.

## The EU MDR Opt-In Process Discriminates Against a Healthier EU

Article 17.1 of the EU MDR requires that Member States “opt-in” to allow reprocessed (*remanufactured* for regulated, commercial and CE marked) SUDs before such products can be sold on their territories. This has a chilling effect on regulated remanufacturing because, while many hospitals may prefer the practice of reprocessing for its benefits, they may not be able to use it. This barrier exists despite that CE certificates have been issued for remanufactured products to indicate that the devices have met regulatory requirements. This places a stifling burden on medical device remanufacturing and discourages a circular economy in the medical device sector.<sup>2</sup>

AMDR can find no other example where a carve out exists in EU regulations whereby Member States are allowed to prospectively reject CE-marked products, absent safety concerns (The Safeguard Clause, Article 8, MDD).<sup>3,4</sup> We believe strong pressure from original device manufacturers, relying on a volume-based sales culture in healthcare, has resulted in the incongruent and restrictive regulatory playing field<sup>5</sup> disfavoring reprocessing. To advance a circular economy, this must change.

Further, this anti-competitive provision runs counter to sound science and good environmental policy. To allow Member States to supplant their judgment, without any evidence or review of the scientific data ordinarily required of a product seeking market placement, undermines the purposes of the EU MDR and circumvents the Notified Body procedure. This also runs afoul of decades of EU law that allows the free circulation of CE-marked products to be sold across the Union.<sup>6</sup> Allowing Member States to prohibit remanufactured devices or the export of devices to

---

<sup>2</sup> See Article 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”, Regulation (EU) 2017/745 of the European Parliament and of the Council, 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.

<sup>3</sup> Article 8, European Council Directive 93/42/EEC 14 June 1993 concerning medical devices.

<sup>4</sup> Case law establishes that exceptions to the free movement of goods is to be interpreted strictly. *Commission of the European Communities v Kingdom of Spain*. Case C-88/07. It requires Member States impose a national ban on a product to show that the measure is necessary and that the marketing of the products poses a serious risk to the public health and that those rules are in conformity with the principle of proportionality. This includes providing relevant evidence such as technical and scientific data and all other relevant information. *Case C-270/02 Commission v Italy* [2004] ECR I-1559.

<sup>5</sup> Restrictions on the free movement of goods must be proportionate to the aim pursued and not attainable by measures less restrictive on intra-Community trade. *Cassis de Dijon C-470/93*.

<sup>6</sup> Article 26, TFEU, “The Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, in accordance with the relevant provisions of the Treaties,” and “[t]he internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties.”

be remanufactured, violates the fundamental freedoms of the internal market<sup>7</sup> and cannot be justified as protecting public health.

This additional national law requirement deprives many in the EU of access to safe, lower cost and environmentally friendly medical device options. The “opt-in” provision creates an enormous disincentive for European hospitals to be good environmental stewards or to build resiliency in the supply chain, by participating in the remanufacturing process. We strongly urge the Commission to have this section of the Regulation stricken.

### **Elements of Article 17 of the MDR Are a Failure**

Articles 17.3 and 4, which allow hospitals (in-house) and third-parties to reprocess SUDs, are required, under 17.5, to have a Notified Body certify their compliance with the “Common Specifications” (CS). However, since passage of the MDR, no Notified Bodies have certified hospital or third-party Common Specification reprocessing. There is no lawful way for hospitals in Europe to reprocess in accordance with the CS. Therefore, Member States that have allowed this are in violation of article 17.5 of the EU MDR – and they are putting patients at risk. The Commission should take action to make Notified Bodies available to certify CS reprocessing.

AMDR requests that the Commission educate Member States on the CS requirements as there has been inconsistency and non-compliance across the Member States. For example, some Members States have elected to allow CS reprocessing (17.3) but do not allow CE reprocessing (17.2). This makes no sense and AMDR believes this contravenes the regulation which allows Member States to “opt in” to allowing CE marked devices (17.2) and such Members States, “by way of derogation from paragraph 2,” may also allow hospitals to reprocess meeting CS standards. AMDR does not believe it was the Parliament’s intent to allow Member States to allow CS reprocessing and not allow CE reprocessing.

### **Pandemic Preparedness and Supply Chain Shortages Continue**

COVID-19 and climate change have put focus on the vulnerability and wastefulness of the healthcare supply chain. Current EU policy, as discussed in this paper, places a prohibitively

---

<sup>7</sup> Articles 34 and 45, TFEU prohibit quantitative restrictions, and measure having an equivalent effect, on imports and exports between the Union’s Member States. The prohibition of such restrictions covers all commercial rules enacted by the Member States that are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade.\* A ban on the market of a specific product, which has been done here, is the most restrictive measure a Member State can adopt from a free movement perspective. See in particular, Case 8/74 Dassonville [1974] ECR 837, para 5; Case 178/84 Commission v Germany [1987] ECR 1227 (‘Beer purity law’), para. 27; and Case C-12/00 Commission v Spain [2003] ECR I-459, para. 71.

*higher* burden on remanufactured medical devices than exists for original equipment. This is wrong; it frustrates the cultivation of a robust single market and hamstring Member States as they seek to implement more resilient tools to enhance supply chains and help cut carbon footprints.

Articles 17.1 and 17.6 raise the bar for reprocessed devices above what exists for any other medical device. The supply chain disruptions for healthcare products that started during COVID-19 have continued, and they have been particularly onerous for complicated medical devices which contain microchips or rare-earth metals. Removing the regulatory barrier to greater SUD remanufacturing would give EU hospitals access to a simple, immediate way to push back on multiple crises within the healthcare environment. But for overly restrictive regulation in the MDR frustrating the single market, SUD remanufacturers would add more devices and competitiveness to the EU market, as they have in the United States, Canada, United Kingdom and Japan.

### **Healthcare has a Pollution Problem**

Healthcare delivery plays an outsized role in the generation of the greenhouse gases that cause climate change and adverse health effects in humans. In a field committed to health and the premise to “do no harm,” it is unacceptable that the pollution generated from the health sector instead makes people sicker and contributes to the climate change crisis. Medical device remanufacturing spotlights new opportunities to pursue more resilient and less wasteful supply chain practices. Now is the time for the Parliament to support this green technology to address public health emergencies, build supply chain resiliency, fight the threat of climate change, and support a circular economy for healthcare products by amending Article 17 of the MDR.

### **Medical Device Remanufacturing Provides Solutions**

SUD reprocessing and remanufacturing is now strictly regulated in Canada, the United States, Japan, and the United Kingdom with a regulatory foundation also in the EU MDR (though a disharmonized regulatory approach remain, as discussed). As an established practice, with a history of solid regulatory oversight and an impeccable safety record, regulated remanufacturing should serve as a cornerstone activity in the promotion of sustainable healthcare practices. Medical device remanufacturing is a circular solution, advancing supply chain resilience by reducing consumption of new devices, lessening dependency on original equipment manufacturer (OEM) supplies, and extending the life of existing equipment. and creates an industry with jobs. This translates directly to enormous cost savings, substantial reductions in waste and lower

greenhouse gas emissions all while still ensuring a robust supply of safe and effective medical devices.

A growing body of academic research points to medical device remanufacturing as a well-established, proven circular solution that can ensure immediate, measurable benefits. Greater emphasis on SUD remanufacturing would transform the traditional “take-make-dispose” mentality dictating current resource consumption and replace it with a more sustainable, affordable, circular economy model for the larger industry to follow. A regenerative approach to product usage will allow us to consume less, protect the health of populations and the environment, decrease rising costs, and help build a more resilient supply chain for medical devices.

### **Well-Designed Life Cycle Assessments Show a Roughly 50% Reduction in Greenhouse Gas Emissions from Reprocessed Devices**

Researchers from the Fraunhofer Institute for Environmental, Safety, and Energy Technology UMSICHT [published](#) a life cycle assessment of one remanufactured device (an electrophysiology catheter) and found that it reduced ozone depleting emissions by nearly 90 percent and climate change-specific emissions by more than 50 percent compared to an original device.<sup>8</sup> This is only one example of the positive impacts of remanufacturing. A regularly updated list of device life cycle assessments that is peer reviewed is available on [AMDR’s website](#).

### **The Move Away from Disposable Healthcare Culture**

Each year, hospitals across Europe throw out millions of medical devices after just a single use. These devices, labelled for “single-use only,” are not intended by the original equipment manufacturer to be reprocessed or reused *by the health facility*. However, regulatory authorities in the EU, U.S., Canada, and Japan have cleared or approved hundreds of models of SUDs that are remanufactured by regulated, commercial firms. Once remanufactured, liability for the device shifts from the OEM to the remanufacturer. Remanufacturing of SUDs has not resulted in increased patient risk or lesser device functionality, and regulation governing the practice demands remanufacturers produce validated evidence to demonstrate substantial equivalence to original devices.

The health sector accounts for almost 5 percent of all worldwide carbon dioxide emissions, largely from over-reliance on disposable items. If it were a country, the health sector would be

---

<sup>8</sup> Schulte A, et. al., [Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters](#), *Sustainability*, 2021, 13(2), 898.

the fifth-largest emitter on earth, and its CO<sub>2</sub> emissions are *more than twice* those of the entire airline industry.<sup>9</sup> A closer look reveals that more than 80 percent of greenhouse gas emissions generated by the health sector come from its supply chain alone (known as “Scope 3 emissions”).<sup>10</sup>

Action is needed now. More than 40 countries have committed to reducing greenhouse gas emissions generated by the health sector.<sup>11</sup> The EU has also committed to removing regulatory barriers to the development of the circular economy.<sup>12</sup> Given the extent of the sector’s impact on global health, governments and healthcare providers have a responsibility to identify sources of greenhouse gas emissions in the supply chain and find lower emission alternatives such as using remanufactured devices.

## **Background on AMDR**

The [Association of Medical Device Reprocessors](#) (AMDR) represents the worldwide interests of commercial reprocessors (known in Europe as “remanufacturers”) of “single-use” medical devices (SUDs) as a circular economy solution for healthcare. Commercial remanufacturers are regulated under the EU Medical Device Regulation (2017), and in the United States by the Food and Drug Administration (1998). More than 10,300 hospitals worldwide use professional, commercially available remanufactured SUDs. Devices range from non-invasive EKG leads, tourniquet cuffs and pulse oximeter sensors, to invasive devices used in laparoscopic surgery and cardiac imaging devices.

---

<sup>9</sup> [Health Care Climate Footprint Report](#), **Health Care Without Harm**, September 2019.

<sup>10</sup> Eckelman MJ, Haung K, et. al., [Health Care Pollution and Public Health Damage In the United States: An Update](#), **Health Affairs** 39:12. 2071-2079. 2020.

<sup>11</sup> Winston Choi-Schagrin, [More than 40 Nations Pledge to Cut Emissions from their Health Industries](#), **The New York Times**, 8 November 2021.

<sup>12</sup> [How the EU Wants to Achieve a Circular Economy by 2050](#), **European Parliament**, 3 February 2021. See also, [Green Deal: Key to a Climate-Neutral and Sustainable EU](#), **European Parliament**, 22 June 2022.