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United State Trade Representative
Trade Policy Staff Committee
National Trade Estimate Report on Foreign Trade Barriers

Submitted Electronically

Docket: USTR-2024-0015; AMDR Comments **16 October 2024**

Dear Chairwoman Buffa,

The Association of Medical Device Reprocessors (AMDR) – the global non-profit trade association for regulated commercial reprocessors and remanufacturers of single-use medical devices (SUDs) – submits the following comments in response to USTR's request for comments on significant foreign trade barriers for the 2025 National Trade Estimate Report.

Overview: AMDR represents about 95% of the global, regulated commercial SUD reprocessing (*remanufacturing* is the term in Europe) companies. Five of AMDR's six members are in the United States; our other member, one of our smallest, is based in Berlin, Germany.

Over 11,900 hospitals, including all U.S. hospital systems (except for those in the Veterans Health Administration) use regulated reprocessed SUDs from our members. The practice saves hospitals over $465 million, reduces waste and cuts greenhouse gas emissions by roughly 44% compared to using virgin devices.[1] Over 300 kinds of devices labelled for "single-use" by their original manufacturer have been evaluated as safe and effective after reprocessing by FDA and now also by European Notified Bodies.

Market access to the EU for U.S. reprocessors was severely reduced when the EU Medical Device Regulation (MDR) of 2017, as mandated since May 26, 2021, instituted an additional level of individual EU Member State approval, above and beyond the CE marking[2] requirements applicable to all medical devices. About half of the EU Member States allow and the other half disallow or have failed to take action to allow commercially reprocessed medical devices, resulting in EU market reduction for U.S. companies estimated to be worth between $300 million to $400 million U.S. dollars per year, based on current product offerings and similar sales in the U.S. market.

Therefore, AMDR encourages USTR to engage with the EU to open this important market for U.S. companies as the MDR is a non-tariff trade barrier with non-harmonized regulatory standards for reprocessed medical devices. Without changes to harmonize the legislation, the EU MDR contradicts U.S., UK, Canadian, and Japanese policies on SUD reprocessing, in addition to setting forth an illegal trade barrier, in our view, under EU law.

[1] News Release: AMDR Members helped hospitals save over $465mm in 2023
[2] CE marking (an acronym for the French "Conformite Europeenne") certifies that a product has met EU health, safety, and environmental requirements.

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With the MDR potentially up for revisions[3], the European Commission indicated technical amendments will be considered to the original MDR. We encourage USTR to use this opportunity to engage on behalf of U.S. reprocessing companies. Increased reprocessing by U.S. firms increases the number of "green" and "circular economy" jobs here in the U.S., bringing substantial economic benefit. Reforming the MDR will also increase supply chain resilience for critical medical devices, decrease the overall carbon footprint of medical devices, and contribute to a more circular economy, as outlined below.

The EU MDR "Opt-In" Discriminates Against U.S. Firms and Undermines a Healthier EU

Article 17.1 of the MDR requires that EU Member States "opt-in" to allow reprocessed (*remanufactured* for regulated, commercial and CE marked) SUDs before such products can be sold in their territories.[4] This has a chilling effect on regulated reprocessing exports from the U.S. to the EU because, while many hospitals may prefer the practice of reprocessing for its benefits, hospitals are not be able to do so *unless* their Member State has opted-in to allowing such products. This barrier exists even though CE certificates have been issued for reprocessed products, indicating these devices have met regulatory requirements. This places a stifling burden on medical device reprocessing and discourages a circular economy in the medical device sector. This is a higher burden than exists for any other medical device.

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).[5,6] We believe strong pressure from certain original device manufacturers, relying on a volume-based sales culture in healthcare, has resulted in the incongruent and restrictive regulatory playing field[7] 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, circumvents the Notified Body procedure, and effectively bars U.S. reprocessors from the EU market. This also runs afoul of decades of EU law that allows the free circulation of CE-marked products to be

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[3] Mission Letter, Ursula von der Leyen, President of the European Commission, 17 September 2024, "You will ensure the availability and competitiveness of medical devices, including by stepping up the implementation of the current framework and evaluating the need for potential legislative changes."

[4] *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.

[5] Article 8, European Council Directive 93/42/EEC 14 June 1993 concerning medical devices.

[6] 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.

[7] 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.

sold across the Union.[8] Allowing Member States to prohibit reprocessed devices or the export of devices to be reprocessed, violates the fundamental freedoms of the internal market[9] and cannot be justified as protecting public health.

The additional national law requirement deprives many in the EU of access to safe, lower cost, and more environmentally friendly medical device options. The "opt-in" provision creates an enormous disincentive for European hospitals to become better environmental stewards or to build resiliency in the supply chain, outcomes that would be made possible by reprocessing medical devices.

Pandemic Preparedness and Supply Chain Shortages Continue

COVID-19 and climate change have put into focus the vulnerability and wastefulness of the healthcare supply chain. Current EU policy, as discussed in these comments, places a prohibitively *higher* burden on reprocessed medical devices than exists for their virgin counterparts. This is wrong; it frustrates the cultivation of a robust single market and hamstrings 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 of the MDR 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. Removing the regulatory barrier to greater SUD reprocessing 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 reprocessors would add more devices and competitiveness to the EU market, as they have in the U.S., Canada, United Kingdom, and Japan.

Healthcare has a Pollution Problem

Healthcare delivery plays an outsized role in the generation of the greenhouse gases that causes 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 reprocessing spotlights new opportunities to pursue more resilient and less wasteful supply chain practices.

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8 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."

9 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.

The health sector accounts for generating almost 5% of carbon dioxide emissions worldwide, largely from over-reliance on disposable items. If it were a country, the health sector would be the fifth-largest emitter on earth, and health sector C02 emissions are *more than twice* those of the entire airline industry.[10] A closer look reveals that more than 80% of greenhouse gas emissions generated by the health sector come from its supply chain alone (known as "Scope 3 emissions").[11]

Medical Device Reprocessing Provides Solutions

SUD reprocessing is now strictly regulated in Canada, the U.S., Japan, and the United Kingdom with a regulatory foundation also in the EU MDR (though the disharmonized regulatory approach remains, as discussed). As an established practice, with a history of solid regulatory oversight and an impeccable safety record, regulated reprocessing should serve as a cornerstone activity in the promotion of sustainable healthcare practices. Medical device reprocessing 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. 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 reprocessing as a well-established, proven solution that can ensure immediate, measurable benefits. Greater emphasis on SUD reprocessing 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, help mitigate 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 it reduced ozone depleting emissions by nearly 90% and climate change-specific emissions by more than 50% compared to an original device.[12] This is only one example of the positive impacts of remanufacturing. A regularly updated list of peer-reviewed medical device life cycle assessments is available on AMDR's website. On average, these peer reviewed life cycle assessments find a 44% reduction in C02 emissions by using reprocessed SUDs.

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10 Health Care Climate Footprint Report, **Health Care Without Harm,** September 2019.

11 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.

12 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.

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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, the United Kingdom, and Japan have cleared or approved hundreds of models of SUDs that are reprocessed by regulated, commercial firms. Once reprocessed, liability for the device shifts from the OEM to the reprocessor. Reprocessing 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.

Action is needed now. Over 70 countries have committed to reducing greenhouse gas emissions generated by the health sector.[13] The EU has also committed to removing regulatory barriers to the development of the circular economy.[14] 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 reprocessed devices.

Decades of Successful Regulation

Commercial reprocessors are regulated as manufacturers under the EU Medical Device Regulation (2017), in the U.S. by the Food and Drug Administration (FDA)(since 1998), by Health Canada, the Medicines and Healthcare Products Regulatory Agency in the UK, and by Ministry of Health, Labor and Welfare in Japan, among others.

Over 300 kinds of devices labelled for "single-use" by their original manufacturer have been evaluated as safe and effective after reprocessing by FDA and now also by European Notified Bodies. The issue of safety and regulated reprocessed SUDs was put to bed in 2008, when, after nearly a decade of use in thousands of U.S. hospitals, the U.S. General Accounting Office conducted a comprehensive, independent analysis and found no increased risk to patient safety from reprocessed devices.[15] In 2023 alone, our members reported that nearly 12,000 hospitals used over 30 million reprocessed SUDs, saving $465 million dollars. *No increased risk to patient safety has ever been found.*

Reprocessed SUDs must meet all the same requirements as any other medical device in other markets, as noted above, ensuring the collection, repair, cleaning, disinfection or sterilization and testing functions of reprocessing results in products with no change in safety or effectiveness.

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13 Hough, E, Supporting Decarbonization of Health Systems—A Review of International Policy and Practice on Health Care and Climate Change, Curr Environ Health Rep. 2024 Feb 15;11(2):266–278.

14 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.

Reprocessed devices range from non-invasive EKG leads, tourniquet cuffs and pulse oximeter sensors, to invasive devices used in laparoscopic surgery and cardiac imaging devices. AMDR members are subsidiaries of global MedTech companies such as Arjo, Cardinal, Medline and Stryker and also independent, third-party companies such as Innovative Health, and Vanguard AG (Berlin, Germany).

Background on AMDR

The Association of Medical Device Reprocessors (AMDR) represents the worldwide interests of commercial reprocessors of SUDs as a circular economy solution for healthcare. Commercial reprocessors and remanufacturers are regulated under the EU MDR (2017), and in the U.S. by the Food and Drug Administration (1998). More than 11,900 hospitals worldwide use professional, commercially available reprocessed/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.

Conclusion:

Regulated, commercially reprocessed SUDs are safe, effective, and marketed legally around the world. Hundreds of millions of reprocessed SUDs have been used with no increased risk to patient safety. Preventing U.S. companies from exporting to the EU compliant reprocessed medical devices is anticompetitive and obstructs green, cost-effective, and resilient business [models / practices].

Reprocessed products offer the immediate benefits of reduced greenhouse gas emissions, waste, and cost, while simultaneously keeping more devices in circulation, which strengthens the supply chain. We urge USTR to assist in combatting the needlessly restrictive regulatory barriers that exist for U.S. companies wishing to export their reprocessed medical devices and services to the EU.

AMDR remains at your service for further discussions on reprocessing. Please reach out if we can assist.

Thank you.

Sincerely,

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See attached position papers.