AMDR comments to the Autoridade Nacional do Medicamento e Produtos de Saúde I.P., (hereinafter, *Infarmed*):

Decree Law No. XXX/2021: Regarding Reprocessed Single-Use Medical Devices (EU TRIS Notification 2021/0615/P-S10S)

6 October 2021

AMDR appreciates Infarmed's decree clarifying Portuguese policy for reprocessing and remanufacturing of single-use medical devices (SUDs). Portugal's history on this issue is deep, having perhaps been the first EU Member State to adopt a regulatory paradigm for SUD reprocessing (implementation Decision 939/2014) requiring compliance with medical device manufacturer requirements (compliance with the essential requirements of Annex I of the then MDD). AMDR views the new decree as a continuation of Portuguese policy modified to reflect changes in EU law.

Infarmed's decree is timely. The EU Medical Device Regulation (MDR) is now in full force. Hospital reuse of SUDs in Portugal, or any Member State, not in compliance with the requirements and national law, is in violation of the MDR. This decree is needed to provide a legitimate, regulated path for the continued use of reprocessed and remanufactured SUDs and the resulting circular economy benefits they provide: lower waste, reduced greenhouse gas emissions, improved supply chain resiliency and reduced costs.

Over 80% of greenhouse gas emissions from the health sector come from the supply chain, according to published research. Regulated, remanufactured devices represent an immediate opportunity to meet emission reduction goals for the health sector in the wake of climate change. A groundbreaking life cycle assessment published in the journal ***Sustainability*** last December indicates that "using a remanufactured as an alternative to a newly-manufactured catheter shows that the global warming impact is reduced by 50.4% and the abiotic resource use by 28.8%." Cost and waste reductions by using remanufactured devices are also well known. We hope you share this sense of moral obligation and thus the importance of getting this policy right.

Context

Article 17 of the EU MDR of 2017 puts in place stringent new EU-wide requirements for the reuse of SUDs. Member States have discretion on which path or paths to take. In short, any reuse of SUDs, regardless of where it takes place, must both adhere to the safety and efficacy requirements of the MDR and be allowed by national provision. Further, the MDR requires that reprocessors adhere to the same standards as applied to original equipment manufacturers and obtain a CE mark – often dubbed in Europe, "remanufacturing of SUDs" (17.2). Or, Member States may decide "not to apply all of the rules" to allow hospitals to reuse SUDs, in-house, so long as it is compliant with the

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European Commission's 2020 "Common Specifications" (17.3 and 4 (derogation of hospital responsibilities to third-party firms)).

AMDR represents commercial, professional medical device reprocessing and remanufacturing companies and we promote the safety, efficacy, sustainability and supply chain resiliency benefits of reprocessed and remanufactured SUDs, as confirmed by two decades of research done in this area. See AMDR's bibliography here. This is also confirmed by two decades of US FDA and German regulation of the practice. As AMDR members will be the firms to which Portuguese hospitals seek regulated, CE marked remanufactured SUDs subject to this decree, we appreciate this opportunity to provide comment.

Overview

Fundamentally, AMDR is concerned that the Portuguese decree unintentionally intermixes regulated, medical device manufacturing requirements (CE marking) with the authorities granted to Member States pursuant to the Common Specifications (CS) for hospital (or in-house) reprocessing. For clarity, AMDR hereinafter refers to regulated, medical device remanufacturing of SUDs, subject to all the EU MDR requirements (or as outlined in EU MDR 17.2) as "remanufacturing." In-house, or hospital reprocessing of SUDs (or those outlined as only allowed subject to compliance with the CS (17.3 and 17.4), as "reprocessing."

Article 1

Under the EU MDR, Member States may "opt in" to allow reprocessed or remanufactured devices in accordance with article 17.2 of the EU MDR. AMDR understands paragraph 1 of Article 1 to "opt in" to allow EU MDR compliant and CE marked remanufactured devices.

Further, Member States may elect "not to apply all of the rules" to allow hospitals (or subcontractors hired for this purpose) to reprocess SUDs as long as it complies with 17.3's subparts and the CS for in-house reprocessing. AMDR understands paragraph 2 of Article 1 to "opt in" to allowing CS reprocessing of SUDs.

Clarification of Scope

Given the MDR specifically allows only these two paths, and given most of the Articles outlined in the proposed decree limit their scope to "paragraph 2 of article 1," or the CS route, we respectfully ask Infarmed to explicitly make clear that:

- Article 1, subpart 1 specifically opts into the EU MDR's 17**.2** provision requiring CE marks; AND
- Article 1, subpart 2, and all other sections, reference EU MDR Article 17**.3/4,** the CS required of in-house reprocessing.

To be clear, devices subject to 17.2's provisions are held to all EU MDR requirements, must demonstrate conformance with the regulation's requirements, be certified by a Notified Body and bear a CE mark – like any other device placed on the market. CS

reprocessed devices need not comply with all MDR requirements but may be subject to additional restrictions by the Member State, such as those outlined in Articles 3 to 13.

Article 7

While AMDR members are primarily focused on providing EU MDR compliant (CE marked) remanufactured SUDs to Portuguese hospitals, we don't know all the future foretells. Therefore, we provide comments on the prohibitions outlined in Article 7.

We urge Infarmed to reconsider the restrictions in subpart 1 of Article 7. The European Commission's preamble language to the Common Specifications notes that many devices "could be considered unsuitable for reprocessing," (emphasis added) but those devices are not, per se, prohibited, nor does the Commission suggest so much. Infarmed goes a considerable step further and prohibits, without evidence, the reprocessing of many SUDs that are already being commercially reprocessed, and subject to Notified Body oversight. We urge Infarmed to instead require hospital reprocessors to, as the Commission language suggests, "include the analysis of the characteristics of the single-use devices in terms of construction, material, properties and planned application, in order to assess the suitability of such single-use devices to be taken into account within risk management procedures."

Without modification, the prohibited device list is so vast, no devices would be eligible for CS reprocessing, making most of the Articles of this Regulation moot. For instance:

- Subsection D would eliminate devices "invasive . . to the central circulatory system." EP catheters, for example, have been safely reprocessed and remanufactured for over two decades as evidenced by the regulated product offerings from AMDR members and substantial peer-reviewed research. There is no evidence to suggest that vascular devices in compliance with requirements present any increased risk.

- Subsection H would eliminate all devices with a battery when, currently, many devices with batteries (both multiple use and single-use) are reprocessed.

- Subsection I would eliminate all devices with internal data storage, but considerable efforts have been taken, at least by commercial reprocessors and remanufacturers, to assess and account for concerns stemming for data storage in devices.

- Subsection J would eliminate virtually anything else that is reprocessed with its inclusion of "cutting or scraping blades." For all the reasons outlined above, a broad-based and prospective prohibition is counterproductive.

- Subsection 5 ensures that CS reprocessed devices are not "placed on the market" or do not bear a CE mark, however the provision goes too far, prohibiting acquisition or transfer of devices. This would effectively undermine the entirety of the regulation as hospitals cannot contract with regulated third parties to acquire and transport devices.

For the reasons noted above, the prohibitions proposed would effectively reduce the pool of eligible SUDs for reprocessing to nothing, undermining the purposes of any regulation purportedly set to outline the safety requirements of such products.

AMDR appreciates this opportunity to comment. If we can be of further technical service, please do not hesitate to contact us. Please feel free to contact me directly if any of these comments are unclear. But we hope Infarmed will clarify between CE marked, remanufacturing as distinct from the requirements proposed for CS reprocessing of SUDs.

About AMDR

The Association of Medical Device Reprocessors is the global trade association for the regulated, professional single-use device reprocessing and remanufacturing industry. For 20 years, AMDR has promoted reprocessing remanufacturing as an important healthcare strategy that helps hospitals and healthcare providers increase quality, reduce costs, and strengthen the supply chain. AMDR protects the interests of its members in regulation, legislation and standard-setting.

AMDR members include Innovative Health, Medline Renewal, NEScientific, ReNu Medical, Stryker Sustainable Solution, Sustainable Technologies (a Cardinal Health Business), and Vanguard AG.

Having played a key role in the establishment of the reprocessing industry, AMDR continues to push the global medical technology industry and lead the way for remanufacturing to play a defining role in the evolution and use of new device technologies.

Sincerely,

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