AMDR Position on the European Medical Device Regulation:
Proposal for a Regulation of the European Parliament and of the Council of the on Medical Devices and Amending Directive 2001/83/EC

The Association of Medical Device Reprocessors (AMDR)[1] congratulates the European Commission, Council and Parliament on efforts of this last year to complete the European Medical Device Regulation (MDR) and reach an agreement on the reprocessing of single-use device (SUD) provisions. Fundamentally, AMDR strongly supports the core premise of Article 17 that the reprocessing SUDs will be held to the same standards applied to all other medical device manufacturers. Upon implementation, all entities that reuse SUDs (original equipment manufacturers, third-party firms and hospitals) are subject to the same medical device manufacturer requirements – leveling the regulatory playing field.

AMDR believes that Member States that opt in to Article 17's CE marking requirements for reprocessed SUDs (originally article 15) will seize the opportunity to stop inappropriate, unvalidated in-hospital reuse of SUDs while allowing safe, commercial, regulated remanufacturing to continue, thereby allowing hospitals to reduce costs and medical waste.

17.1: "Opt In/Opt Out"
The final MDR is not the single, harmonized approach AMDR had hoped for in that Member States must still opt in to allowing CE marked remanufactured SUDs on their market. Therefore, AMDR is actively meeting with the various Member States, encouraging them to opt in to the requirements to help stop inappropriate in-hospital reuse, encourage only safe remanufacturing by regulated firms, and promote reduced healthcare costs and waste.

AMDR specifically encourages Member States to make public communication to healthcare stakeholders within their borders to:

- Explicitly opt in to the European MDR's Article 17 paradigm for SUD reuse;
- Communicate to providers that, upon implementation, stringent new EU rules will preclude hospitals and healthcare providers from reusing SUDs without meeting manufacturer requirements or stringent Common Specifications as published by the Commission;
- Clarify to stakeholders that reuse of SUDs, not in compliance with the new requirements, make the healthcare facility legally and regulatorily responsible;
- To alert hospitals to the availability of CE marked, remanufactured SUDs that do meet the MDD and MDR requirements; and thus

[1] AMDR is the trade association representing the global "single-use" device (SUD) reprocessing and remanufacturing industry. AMDR members serve a majority of U.S. hospitals and over 1,000 European hospitals. In fact, AMDR's members serve most of the U.S. "honor roll" hospitals, as listed by *U.S. News & World Report* (2016-2017), and 95 percent of German university medical centers. AMDR's core mission is to promote the proper reprocessing and remanufacturing of SUDs. For more information about AMDR, please visit www.amdr.org.

- Promote safe, regulated CE marked remanufactured devices as a legitimate alternative hospital and healthcare providers may use to reduce costs and healthcare waste.

17.3 In-Hospital "Carve Out"

Subsection 17.3 of the MDR does propose to allow in-house or hospital reuse of SUDs under certain conditions. AMDR does not support adopting this different standard for SUD reuse other than full manufacturer treatment. Patients and healthcare providers across Europe should know that all reprocessed or remanufactured SUDs on the market meet the same safety requirements as any other medical device.

17.3, in AMDR's view, will ultimately have little impact and we therefore discourage Member States for pursuing a path that would allow for in-hospital reuse. At a minimum, 17.3 already requires that hospitals wanting to reuse SUDs in-house must have a risk management program in place which includes the "analysis of the construction and material, and related properties (reverse engineering)" of the device, have a quality management system, have validated all procedures and conduct product release and performance testing, to name a few examples, plus meet forthcoming "Common Specifications" to be released by the Commission, and compliance with all the Common specifications shall be certified by a notified body. AMDR does not believe hospitals are able to meet this standard. Thus, while we have yet to see what the Common Specifications will be, we believe this high standard will ultimately steer hospitals to commercial, regulated, CE marked remanufactured SUDs rather than use in-house.

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AMDR congratulates the European Commission, Council, the Parliament and the Dutch Presidency for its commitment to establish a regulatory framework for SUD reprocessing and remanufacturing that ensures patient safety. AMDR's members are eager to demonstrate to hospitals that their products meet manufacturer requirements and lower costs and medical waste.