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AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

Comments from the Association of Medical Device Reprocessors
European Commission's Public Consultation on the Circular Economy
20 August 2015

The Association of Medical Device Reprocessors (AMDR) applauds the Commission's Circular Economy initiative and urges consideration of the effects of healthcare waste. The reprocessing of a select number of medical devices labeled by the original manufacturer as for "single-use" safety extends the life and value of expensive medical instrumentation, reduces demands on nature resources, eliminates medical waste and repurposes valuable materials such as gold, platinum, steel and plastics. The nascent commercial medical device reprocessing industry, if properly promoted, has the potential to save EU hospitals hundreds of millions of Euros a year, reduce hazardous medical waste, increase recycling, and drive job growth in the reprocessing industry.

The pending *Proposal for a Regulation of the European Parliament and of the Council of the on Medical Devices and Amending Directive 2001/83/EC* ("Proposal") would establish an EU-wide regulatory framework for "single-use" device (SUD) reprocessing. AMDR strongly supports the core of the Commission, Parliament and Councils' versions of the regulation which ensure a regulatory pathway for firms to market reprocessed SUDs by demonstrating that their products meet manufacturer requirements. This will allow hospitals and providers in the EU the ability to provide safe and effective reprocessed SUDs at less cost, while benefiting the environment.

However, a number of elements of the Council's Proposal would disproportionately burden the budding medical device reprocessing industry, subjecting lower-cost and environmentally-friendly reprocessed medical devices from commercial firms to even more stringent requirements than existed for the original equipment manufacturer (OEM). To promote the competitive benefits of reprocessing, we urge the Commission and negotiators at Trialogue to strongly reconsider several provisions.

<u>One Harmonized Standard for SUD Reprocessors</u>

The Council's Proposal includes measures that would undermine the fundamental principle of a single, harmonized medical device market. Article 15.0 of the Council Proposal subrogates to Member State law by only allowing reprocessing *if* allowed in the individual Member State. Similarly, Article 15.1(a)-(c) creates a separate standard for reuse in health institutions at the Member State level. And Article 15.6 allows Member States to institute stricter national provisions on the subjection of reprocessing. These provisions create an inequitable regulatory system by subjecting reprocessors to *more* stringent requirements than even the OEMs, undermining the harmonized European market and results in varying standards of patient safety. *AMDR recommends striking Article 15.0, 15.1(a)-(c) and 15.6.*

<u>Critical Medical Devices</u>

The Council's Proposal would require the Commission, through implementing acts, to develop lists of categories of devices which cannot be reprocessed (Article 15.4). As the Medical Device Regulation would subject reprocessors to *all* manufacturer requirements, this additional burden is unnecessary,

does not advance patient safety, and, would make reprocessors *more heavily* regulated than the OEMs. *AMDR recommends striking Article 15.4.*

Clinical Evaluation

Finally, access to another manufacturer's technical file is not necessary to demonstrate equivalence as part of a clinical evaluation. Other methods to understand the composition of a product, including tracking device modifications, are available. The requirement risks completely preventing lower-cost, environmentally-responsible devices from coming to market. *AMDR recommends striking the second paragraph of Article 49.2a*.