AMDR Position on the European Council's Partial General Approach to a Proposed 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

On behalf of its member companies, the Association of Medical Device Reprocessors (AMDR),[1] applauds the European Council's efforts regarding its Medical Device Regulation proposal ("Council's Proposal"). Overall, AMDR strongly supports a number of measures in the Proposal. Significantly, the Council secures a regulatory pathway for firms to market reprocessed/remanufactured "single-use" devices (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. We, however, request that Trialogue negotiators strongly consider several necessary revisions to Article 15 and 49 to ensure clarity and fairness in the final Regulation. AMDR's suggested considerations and revisions include the following:

AMDR Urges One Harmonized Standard for SUD Reprocessors/Remanufacturers
The Council's Proposal includes measures that would undermine the fundamental principle of a single, harmonized medical device market. Although this is an EU Regulation meant to apply a single standard for all Member States, Article 15.0 subrogates to Member State law by only allowing reprocessing *if* allowed in the individual Member State. This creates an inequitable regulatory system, subjects reprocessors to *more* stringent requirements than even original equipment manufacturers, and begins to unravel the very concept of what it means to be CE marked. *AMDR therefore urges negotiators at Trialogue to strike Article 15.0.*

Also, Article 15.6 allows Member States to institute stricter national provisions on the subjection of reprocessing, also undermining the principle of a harmonized market by creating disparate regulatory treatment amongst reprocessors and the Member States. There is no basis demonstrating that reprocessed SUDs that meet CE marking requirements pose any greater safety threat than new devices. Further, allowing stricter treatment for a subset of the device industry would subject reprocessors to more stringent requirements than even original equipment manufacturers. *AMDR therefore urges negotiators at Trialogue to strike Article 15.6.*

Reprocessing of Critical Medical Devices
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

[1] AMDR is an international trade association representing commercial reprocessors/remanufacturers of medical devices labeled by their original manufacturer as for "single-use." AMDR members perform a majority of the third-party reprocessing conducted in the United States and serve over 1,000 European hospitals.

unnecessary and does not advance patient safety. AMDR agrees that many devices cannot be reprocessed, but, as with any other medical device, the regulatory framework protects public health by not allowing devices that do not meet standards to obtain a CE mark. Further, inclusion of an additional listing restriction against reprocessors and not other medical device manufacturers, coupled with the Member State 'opt in" requirements, would make reprocessors *more heavily* regulated than any other subset of the medical device manufacturing industry – an unfair and anticompetitive burden. *AMDR urges negotiators at Trialogue to strike Article 15.4.*

Clinical Evaluation

Access to another manufacturer's technical file is not possible nor necessary to demonstrate equivalence as part of a clinical evaluation. Moreover, practically speaking, the sharing of such information may involve trade secrets and proprietary information that manufacturers do not share and are not required to share with other manufactures in the ordinary course. Other methods to understand the composition of a product, including tracking device modifications, are available. Thus the requirement that there be a "contractual" relationship between competing manufacturers is impractical and unnecessary (Article 49.2a) and risks completely preventing lower-cost, environmentally-responsible devices from coming to market. *AMDR urges negotiators at Trialogue to strike the contractual requirement from the second Article 49.2a*.

Conclusion

AMDR strongly believes that the disproportionate and significantly more burdensome measures outlined for reprocessors in 15.0, 15.4, 15.6 and Article 49, violate the principle of proportionality outlined in Article 5(4) of the Treaty on the Functioning of the European Union (TFEU). Further, such disproportionately burdensome requirements applied to reprocessors, and not all other device manufacturers, runs against the principals of the internal market.

AMDR congratulates the European Council and the Latvian Presidency for its commitment to establish a regulatory framework for SUD reprocessing and remanufacturing ensuring patient safety. AMDR members are eager to demonstrate to Competent Authorities and Notified Bodies that their products indeed do meet manufacturer requirements and are entitled to CE marking.