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AMDR response to Dutch Medical Aids Decree
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The Association of Medical Device Reprocessors (AMDR) respectfully submits the following comments in response to the 24 April 2019 Medical Devices public consultation. AMDR and its members are appreciative of the time and effort the Dutch Ministry has invested in this issue. We are confident, with implementation of the new EU Medical Device Regulation (MDR) and additional rules in place in the Netherlands, Dutch hospitals will choose regulated and safe reprocessed single-use devices (SUDs) to reduce costs and waste.

AMDR is the global trade association consisting of members of the commercial single-use device reprocessing and remanufacturing industry. AMDR represents regulated, commercial reprocessing and remanufacturing, promotes reprocessing and remanufacturing as an important healthcare strategy that helps hospitals increase quality, reduce costs and improve patient care, and protects the interest of its members in regulation, legislation and standard-setting worldwide.

AMDR members operate in Europe, the U.S., Canada and Japan, among other markets, as regulated medical device manufacturers, subject to all the same requirements as any other medical device maker. AMDR members will fulfill all manufacturer requirements of the EU MDR. The proposed rulemaking goes further, setting forth additional requirements of reprocessors offering their products in the Netherlands market. We therefore respectfully ask for your consideration to the following:

Article 4: Reprocessing Medical Devices for Single-Use
AMDR supports the Dutch rulemaking's efforts to ensure that SUD reprocessors set a maximum number of times a medical device is safe to be reprocessed. That said, proper manufacturing validations would, nevertheless, be required of reprocessors as part of the EU MDR's requirements. Thus, we believe the Dutch requirement is duplicative. However, we have no objection to its inclusion, making certain only reprocessed devices with proper validations in place, limiting devices to a set number of cycles, are placed on the Dutch market.

Article 5: Prohibitions of Reprocessing
Respectfully, AMDR strongly objects to the inclusion of the prospective list of devices prohibited from reprocessing. AMDR and its members agree that medical device exposure to prions may necessitate special precautions, but our responsibilities as manufacturers include having proper cleaning and sterilization validations to assess for this, and any other iatrogenic concern. Such a list sets a dangerous precedent, prospectively, or before evidence has been evaluated, declaring what can and cannot be done. We therefore urge the removal of this article.

First, inclusion of a prohibited lists ignores reprocessors' expertise. Professional reprocessing firms, under the oversight of Notified Bodies and Member States' Competent Authorities, have

far more expertise in evaluating whether medical devices may be reprocessed. Similar to the development of any new medical device, innovative developments should be left to industry and the certification of compliance functions left to Notified Bodies and Competent Authorities. Medical device reprocessors are the medical technology industry's leading experts in the fields of medical device cleaning, sterilization and functional performance testing. There are constant advancements in this field and prospectively placing a prohibitive list on one segment of the industry, without evaluating the risks and data first, seems improper. AMDR agrees that many devices cannot be reprocessed, but, as with any other medical device, the EUs MDR regulatory framework already protects public health by not allowing devices that do not meet standards to obtain a CE mark.

Second, inclusion of a prohibited list does not address patient safety. AMDR member reprocessors do not currently reprocess any of the devices noted in the draft list. However, no such prohibition exits for hospital reuse of reusable devices that may come into contact with the same tissues noted in the proposed list. Therefore, real risk of prion exposure, if it is a serious one, lies with what hospitals are already doing with their own instruments and in their own reprocessing departments – not with commercial reprocessors. Therefore, the proposed list of prohibited devices for commercial SUD reprocessors, but not hospitals, does not advance patient safety and places an undue burden on the professional industry.

Third, a prohibited listed is unduly burdensome. Earlier drafts of the EU MDR did contemplate inclusion of a "negative list" of devices (those that cannot be reprocessed). Ultimately this approach was rejected. The MDR already subjects reprocessors to all manufacturer requirements (as noted in paragraph above), and so Member States adopting further negative lists would place additional burdens on industry that is unnecessary and does not advance patient safety. Having each EU Member State decide what cannot be professionally reprocessed would be unduly burdensome to both every Health Ministry in the EU and industry, would needlessly restrict trade and competition, and inverts the well-accepted roles of regulated and regulator. 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.

We thank you for your consideration.

Respectfully submitted,

Daniel J. Vukelich, Esq.
President
Association of Medical Device Reprocessors
DVukelich@amdr.org