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AMDR Statement

FDA's Recently Published Guidance Document, "Remanufacturing of Medical Devices," Addresses Reusable Devices, not Reprocessed Single-Use Devices

[Washington, D.C. – June 4, 2024] On May 10th, 2024, the U.S. Food and Drug Administration issued final guidance titled, "Remanufacturing of Medical Devices: Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff."

AMDR wishes to highlight that the guidance "is not intended to address reprocessed single-use devices" and instead addresses the remanufacturing of reusable devices, according to the document. AMDR offers this clarification to help readers draw the distinction between FDA-regulated, commercially reprocessed single-use devices (rSUDs) and reusable, remanufactured devices.

FDA-regulated commercially reprocessed single-use devices reduce cost, waste, and greenhouse gas emissions while strengthening the supply chain. A growing body of peer reviewed life cycle assessments finds that rSUDs reduce greenhouse gas emissions by 41% on average compared to using virgin devices each time.

rSUDs are fully regulated by FDA and thus reprocessors must meet all medical device manufacturing requirements, including pre-market review. The FDA began regulating single-use device reprocessing in 2000, and additional stringent cleaning, testing and performance testing requirements were amended in 2002 as part of the Medical Device User Fee Modernization Act. With one exception, every hospital system in the United States, including 70 U.S. military hospitals, use commercially reprocessed single-use devices. Only the Veterans Affairs Hospitals does not use rSUDs.

About AMDR

The Association of Medical Device Reprocessors (AMDR) is the global trade association for the regulated, commercial "single-use" device reprocessing and remanufacturing industry. Founded in 1997, AMDR has advocated for reprocessing and remanufacturing as an important healthcare strategy that helps hospitals and healthcare providers increase quality, reduce costs, waste, and emissions, and strengthen the supply chain.

AMDR protects the interests of its members in regulation, legislation, and standard-setting. AMDR members include Arjo ReNu Medical, Innovative Health, Medline Renewal, 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, leading the way for remanufacturing to play a defining role in the evolution of new device technologies.

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