NEWS

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

For Immediate Release

First Global Regulatory Standards for "Single-Use" Medical Device Reprocessing and Remanufacturing Published by the Association of Medical Device Reprocessors

[Washington/Berlin June 7, 2022] When health systems and hospitals use regulated reprocessed "single-use" devices, they reduce procedure costs without compromising patient safety, build supply chain resilience and help governments and hospitals get to net zero carbon emissions faster. Given the dual threats of disruptive pandemics and climate change, regulators worldwide must act now to usher in responsible, regulated medical device reuse regulation. But regulations and standards for the practice are difficult to find and have never been available in one place.

The Association of Medical Device Reprocessors is pleased to share **"Global Regulatory Standards for 'Single-Use' Medical Device Reprocessing and Remanufacturing,"** the first roadmap to help Notified Bodies, Ministries of Health, and regulatory authorities of medical devices to unlock these benefits for hospitals and health systems worldwide. The report includes all known regulations, standards, and guidances that govern the practice of reprocessing (known as remanufacturing in Europe), worldwide.

Reprocessing single-use medical devices saves hundreds of millions of dollars a year. But savings could go into the billions. According to a report issued by AMDR last week, hospitals in the U.S., which has the most robust reprocessing programs in the world, could reprocess an additional $2.28 billion, if those with existing programs reprocessed as much as the highest 10% performing hospitals.

The report is available through a simple registration process here.

"Our 'disposable' culture in healthcare is not financially or environmentally sustainable," said Daniel J. Vukelich, Esq., President and CEO, Association of Medical Device Reprocessors. "Hospitals that reprocess SUDs reduce greenhouse gas emissions, costs, and waste. Our Global Regulatory Standards report provides a roadmap for regulatory authorities in more countries to create legal, safe, and effective processes for more hospitals to cut waste."

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In 2000, the U.S. Food and Drug Administration became the first regulatory authority in the world to create a pathway for commercial SUD reprocessing, discouraging the practice from occurring within hospitals. Today, over 31 million SUDs are reprocessed and safely reused without any increased risk to patient safety. FDA considers the devices "substantially equivalent" to original devices. The EU allows member states to "opt-in" to reprocessing, and the UK allows the practice under a similar regulatory scheme to that in the U.S.

"From our inception, AMDR has believed that a strong regulatory framework provides the best path for hospitals to reduce waste and cut costs," said Mr. Vukelich. "We are proud to help as many hospitals as possible to build a circular economy in healthcare."

About AMDR
The Association of Medical Device Reprocessors is the global trade association for the regulated, commercial single-use device reprocessing and remanufacturing industry. For 22 years, AMDR has promoted reprocessing and remanufacturing as an important healthcare strategy that helps hospitals and healthcare providers increase quality, reduce costs, 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, NEScientific, 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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