# AMDR Reaction to Swedish MedTech Shadow Report

**(January 2021)**

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**Key Findings:**

- The Swedish MedTech "Shadow Report" shared misinformation and an inaccurate understanding of Article 17, putting profits of original equipment medical device makers (OEMs) over facts and science.
- Under the new MDR and Common Specifications, remanufacturing of single-use devices must adhere to the identical safety and efficacy requirements as required of OEMs—including obtaining a CE mark.
- Regulated remanufacturing in industrialized nations dates back decades, saving health systems billions of Euros with no increased risk to patient safety.
- The remanufacturing of single-use devices is a leading solution for the health sector's urgent need to create a more Circular Economy. It significantly reduces greenhouse gas emissions and the cost of healthcare, while increasing supply chain resiliency – vital for fighting the pandemic.
- The Association of Medical Device Reprocessors urges the Swedish National Board of Health and Welfare to reject the findings of the "Shadow" report.

In December 2020, the Swedish National Board of Health and Welfare (Socialstyrelsen) released a thorough and evidenced report: *Prerequisites for Reprocessing and Reusing Disposable Medical Devices* (original, and AMDR's English version). The Association of Medical Device Reprocessors (AMDR) applauds the Swedish National Board of Health and Welfare's work. Our statement on the report and its conclusions is available here.

## Background

Article 17 of the European Union's Medical Device Regulation (MDR) of 2017 puts in place stringent new EU-wide requirements for the reuse of "single-use" devices (SUDs). EU Member States have discretion on which path or paths to take, as outlined in the

provisions of article 17, and the EU MDR is to be fully implemented by May of this year (2021). In short, any reuse of SUDs must both adhere to the safety and efficacy requirements of the MDR and be allowed by national law. The safety and regulatory requirements ensure reprocessors adhere to the same standards as applied to original equipment manufacturers (OEMs) and obtain a CE mark – often dubbed in Europe, "SUD remanufacturing" (the 17.2 provisions).

Alternately, Member States may elect to allow hospitals to reprocess SUDs in compliance with the European Commission's 2020 "Common Specifications," which apply to hospital "reprocessing" (the 17.3 and 4 provisions). The Swedish National Board of Health and Welfare (hereinafter, the Swedish Authority) was assigned the task of investigating whether "from a patient safety perspective, there are conditions to allow disposable medical devices to be reprocessed and reused in Sweden."

The report concluded, consistent with the long-standing evidence surrounding the regulated medical device reprocessing and remanufacturing industry, that the evidence supports SUD reprocessing for certain device types. The report also finds financial, sustainability, and supply chain resiliency benefits, especially in light of lessons learned from COVID-19.

AMDR applauds the regulation in the EU of SUD reprocessing and remanufacturing. SUDs are often invasive devices, and reuse absent adherence to standards can lead to patient safety issues. AMDR advocates for safe reprocessing and remanufacturing under appropriate regulatory oversight. Our members save healthcare systems almost €500,000,000 a year and divert more than 7,000,000 kilos of waste from the landfills – without any added risk to the patient.

**Swedish MedTech Response**

In response to the Swedish Authority's report, the Swedish MedTech and Sterile Technology Association (*hereinafter*, MedTech) prepared a lengthy written response. Self-dubbed as a "shadow report," the medical device makers have doubled down on dispensing misinformation and promoting an inaccurate understanding of Article 17 to discourage or dissuade stakeholders from reprocessing and remanufacturing. AMDR urges stakeholders to discount the MedTech report as it makes claims without evidence.

Further, it promotes consumption over conservation, supply chain dependency on these device firms over supply chain resiliency, a linear, wasteful "take-make -waste" culture versus a circular economy and, not surprisingly, higher medical device company profits over more prudent allocation of limited healthcare financial resources. And based on research released recently in the journals, *Sustainability*[1] and *Health Affairs*,[2] we know this disposable culture promotes greenhouse gas emissions over $CO^2$ reductions.

AMDR encourages stakeholders to understand the provisions and requirements of article 17 and not to confuse, as MedTech does, historical unregulated *reuse* of SUDs with regulated reprocessing and remanufacturing as they now exist under the new law.

The Swedish authority, and over-arching Health Ministry, would provide an enormous service to hospital systems throughout Europe by rejecting MedTech's shadow report and encouraging manufacturers to become part of the circular healthcare solution.

**Healthcare Sustainability: We Must "Do No Harm"**

According to Healthcare Without Harm, if the global healthcare sector were a country, it would be the fifth-largest greenhouse gas emitter on the planet. Pollution from hospitals adversely impacts human health. Wastefulness in healthcare destroys our environment, while the disposal and incineration of "disposable" healthcare waste is making people sicker. The single-use mindset weakens our supply chain by keeping Europe and the US dependent on foreign manufacturing of "cheap" and allegedly readily available disposable alternatives[3] (though COVID has zeroed in on the weaknesses in our supply chain, resulting in shortages of critical medical supplies at the most urgent time).

Two recent articles in the Journal *Health Affairs*[4] underscore the dramatic harm our disposable healthcare culture creates and call on the device industry to transform to a circular economy. In Transforming the Medical Device Industry: Road Map to a Circular Economy, Professor Andrea MacNeill and her co-authors find the healthcare supply chain to be among the largest drivers of medical waste, and points to remanufacturing SUDs as a "low hanging fruit" solution.

The future of healthcare requires a move toward resiliency, more local manufacturing and distribution, greater use of limited resources – a circular economy. In the COVID era, where more attention than ever should be focused on supply chain weaknesses and the financial and environmental costs associated with disposable products, we are surprised that Swedish MedTech has committed to a toxic culture of disposability rather than working with healthcare systems, providers and reprocessors to promote a circular economy in healthcare.

Increasingly, responsible medical device manufacturers are choosing to be part of the solution rather than part of the problem. Research continues to pile up in support of reprocessing and remanufacturing programs. Just last month the journal *Sustainability,* published a Life Cycle Assessment demonstrating clear environmental superiority of remanufactured devices over new, "virgin" device use and disposal. The carbon footprint is reduced by 50% through medical remanufacturing. See, Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters, Schulte, Maga and Thonemann, *Sustainability*, January 2021.

Arjo, Cardinal Health, Medline and Stryker – all large and respected OEMS, have turned their back on MedTech's short sighted anti-remanufacturing approach in order to provide sustainable solutions to the healthcare sector and count themselves as AMDR members (along with other European and American stand-alone commercial reprocessors and remanufacturers like Innovative Health, Northeast Scientific and Vanguard AG).

**Detailed Responses**

Below AMDR outlines a detailed response to what we believe are particularly misleading or erroneous claims made in the MedTech shadow report.

***Nomenclature:***

Reuse. Reprocessing. Remanufacturing. Many terms are used to describe the process of cleaning and sterilizing medical devices after initial use to prepare them for another clinical use. In 2017, with the passage of the EU's Medical Device Regulation (MDR), all this changes as any reuse of an SUD must comply with the law's strict new requirements. MedTech, unfortunately, uses the terms "re-sterilization" and "reuse" interchangeably without adequately defining them and more importantly failing to sufficiently acknowledge and make clear to the reader that the law and the standards have changed. In, short, by taking this approach, MedTech attacks not only unregulated reuse but also regulated reprocessing and remanufacturing, and confuses and impugns regulated reprocessing with conclusions based on now illegal, un-regulated "reuse" of devices. This makes the entirety of the MedTech report false and/or misleading.

For purposes of this paper, acknowledging the new EU law:

> *Reuse* is a general term describing simple reuse of medical devices.
>
> *Reprocessing,* as defined, for example, in the new European Medical Device Regulation, means the process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilization and related procedures, as well as testing and restoration of the technical and functional safety of the used device. It is a term most associated with those activities which take place in hospitals and often applies to the reuse of both multiple and single-use devices. In the US and Canada, SUD reprocessing is regulated as manufacturing.
>
> *SUD remanufacturing* is when regulated, commercial firms reprocess SUDs *and* demonstrate compliance with medical device manufacturer requirements. This practice ensures patients and healthcare providers that remanufactured SUDs are as safe and as effective as a new device. As various countries, including the EU, adopt manufacturer regulations for SUD reuse, the term SUD remanufacturing is being adopted instead of reprocessing.

AMDR's members define "reprocessing" as the <u>complete</u> rebuilding of used devices and their assignment to a new useful life (*i.e.*, another "single-use") under the same regulatory conditions that are applicable to the manufacturing of new devices. Indeed, it is AMDR's position that regulated reprocessing or "remanufacturing" of SUDs refers not only to the cleaning, disinfection, and/or sterilisation of medical devices, but also to the testing and restoration of technical-functional safety following their use for the purpose of renewed use. It is our position that remanufactured medical devices must and do, offer the <u>same</u> standard of safety as new products, in terms of their material characteristics and function. Remanufacturing is carried out in a controlled professional environment by a regulated entity according to validated procedural rules complying with the highest quality criteria and taking place within an accredited quality management system.

Our definition of remanufacturing is fundamentally different from even the reprocessing practice that is typically carried out in-house by hospitals. AMDR members employ much more sophisticated cleaning/disinfection, sterilization techniques and function testing

than most hospitals and achieve consistently reliable and reproducible results. Our members demonstrate compliance with the requirements laid out in EU MDR.

Any discussion, evidence, case studies or the like from hospital *reuse* of medical devices, either multiple use or SUDs, is not comparable to regulated reprocessing or regulated commercial SUD remanufacturing – they are not held to the same standards.

***The EU Regulation:***

AMDR is disappointed in MedTech for casting fear and doubt, without supportive evidence, on the adequacy of the EU MDR's requirements for reprocessors and remanufacturers. The law has fundamentally changed the way reprocessors are regulated in the EU. The EU MDR sets forth new requirements for all EU institutions that reprocess single-use devices. As outlined above and in the Regulation, reprocessing of SUDs must be compliant with national law, and either meet the full requirements of the MDR, as any other manufacturer (and obtain a CE mark) or meet the Common Specifications as developed by the Commission. In other words, the requirements represent a *substantial tightening* of reprocessing standards, ensuring that reprocessing can only take place without risk to patient safety.

The MedTech report ignores the fact that commercial medical device remanufacturers must meet *the same* requirements as applied to OEMs and obtain CE marks. This levels the regulatory playing field ensuring remanufactures meet at least the same regulatory requirements as the OEM itself. Even more, remanufacturers must comply with risk management standards just the same as the OEM, but must also establish additional risk management protocols for the remanufacturing itself (not contemplated or not validated by the OEM such as additional cleaning, functional performance and sterilization validations). This results in no regulatory shortcuts and no compromises in patient safety. The MDR and Common Specifications provide a regulatory framework that protects patient safety while allowing for cost and environmental benefits. This comes at a time when healthcare resources are being stretched to the limit.

***The Single-Use Label:***

While AMDR agrees that some SUDs are labeled as such for patient safety reasons, this is not the only reason. Manufacturers of SUDs also have an economic incentive to sell as many devices as possible, and as a result, many devices are labeled "single use" even though they can be safely reprocessed. Further, a higher regulatory burden associated with marketing devices as *reusable* (validating cleaning instructions, for example) provides incentive for manufacturers to label devices as disposable or for single use.

MedTech fails to acknowledge that choosing to label a device "single use" is entirely in the hands of the OEM and that a "single use" label does not necessarily indicate that a device cannot be remanufactured. In fact, OEMs are not required to validate their "single use" designation with Notified Bodies, leading many healthcare systems and providers to perceive OEMs as having an *economic incentive* to market devices

"single-use" when they are actually reusable.[5] *See also* MacNeil, Health Affairs article, December 2020.[6]

***Extent of Regulated Reprocessing/Remanufacturing:***

MedTech falsely claims that "there are few countries that work with proposals to approve this [reprocessing] in their own country." That is incorrect. The US has regulated a now booming SUD reprocessing industry for over 20 years – also holding reprocessors to the same regulatory standards as OEMs. Germany has had a regulated SUD reprocessing industry for 19 years. Canada, Australia, the UK, Japan – all have regulations on the books regulating SUD reprocessing as manufacturing. In light of the new EU MDR requirements, the Netherlands and Belgium have already "opted in" to allowing such products; the UK and Turkey have agreed to allow such products to harmonize with EU requirements; Ireland, Germany, Norway, Portugal and Slovenia all intend to take action by the May 2021 deadline to allow such products to one degree or another.

***Patient Safety Issues and Double Standards***

Many pages of the MedTech report are written to cast doubt on the cleanliness, functional performance and sterility of reprocessed or remanufactured devices, but no adequate evidence is provided. MedTech also alleges there will be increased "costs" due to shortcomings in these areas, but does not substantiate this claim.

MedTech raises the concern that cleaning and chemical processes will "damage" products, cause elevated infection risk and contribute to antibiotic resistance, etc. As one example, MedTech claims that, with regard to commercial remanufacturers, "there is no guarantee that this means that an adequately documented risk management process has been applied." None of this is supported by evidence obtained from EU MDR compliant reprocessed and remanufactured devices. There is no reason to expect that a Notified Body and competent authority would NOT require compliance with risk management standards, for example, of a reprocessor while they do so for the OEM. In fact the law requires such compliance, from both the OEM and the remanufacturer.

MedTech argues that it is impossible for a reprocessor or remanufacturer to fully understand the construction of a device if they are not the original manufacturer or have access to the original manufacturers data. MedTech seems to argue that reprocessors and remanufacturers must, "in practice have an agreement that ensures that you always have access to the latest knowledge." This is not true as a matter of regulatory policy, safety, or as a matter of law. Like any manufacturer, reprocessors and remanufactures must demonstrate to the Notified Bodies' satisfaction the material composition of the device and, in the case of reprocessing, validate all subsequent reprocessing steps to ensure no compromises in material function or design, among other things. MedTech appears to be making an anti-competitive argument, not a patient safety argument. Legal and regulatory responsibility for their products falls to the manufacturer, or the re-manufacturer. The OEM is neither responsible for nor relevant to a Notified Body's review of a remanufacturer's products.

The same is true for sterilization, packaging, quality systems, or any other standard. The crux of the entire MedTech report requires the reader to believe that somehow the very medical device manufacturing standards applied to manufacturers is insufficient as a safeguard for remanufacturers. This is false, misleading and not supported by any evidence. It is also logically inconsistent unless the MedTech wants to argue that the standards are also inadequate for its own member's products.

MedTech also fails to mention the Common Specifications requirements applicable to hospital reprocessing of single-use devices (so called, in-house reprocessing). These specifications were established by the Commission after extensive consultation with stakeholders and Member State experts. Therefore, MedTech calls into question the authority of the technical experts themselves in regard to the established health standard. MedTech makes theses wild claims without providing any evidence indicating where the Specifications have been insufficient, or where they represent a public health concern.

MedTech also argues that there is a lack of evidence for the safety of reprocessing in the clinical literature. This is false, as can easily be shown by a review of AMDR's lengthy bibliography of articles on the safety of reprocessing and remanufacturing.[7] More importantly, as MedTech knows but refuses to acknowledge, the safety standard for marketing a product in the EU is not a lengthy body of literature, but conformity with the requirements of the EU MDR. This is true for OEMs as well as for Remanufacturers.

To suggest, without evidence for why it is necessary, that a higher standard should exist for their remanufacturing competitors begins to cross the line from fierce marketplace competition into anti-competitive behavior. MedTech cannot, without evidence, argue their competitors should have to adhere to a higher standard than the one to which they themselves are held.

***Irrelevant and Misleading Studies***

As to the studies referenced, the MedTech report includes Appendix I, which purportedly "gives a clear picture of the risks and the uncertainly that surrounds the area." The so called "evidence" in Appendix II consists of two case studies prepared by the Sterile Technology Association. These appendices are false and misleading as they do not apply to the subject matter of regulated reprocessing of single used devices. Bronchoscopes, endoscopes and duodenoscopes, so far as AMDR is aware, are *reusable*, or multiple use devices, cleaned in hospitals pursuant to OEMs' validated cleaning instructions. This is an apples-to-oranges comparison and is a willfully misleading characterization of the issue at hand and not evidence of anything related to SUDs. If there are issues identified there, these are potentially related to MedTech Member's own cleaning instructions or the inability of hospitals to comply with them. But it has absolutely nothing to do with the regulated reprocessing of single use devices.

In the EU MDR – as in other reprocessing regulations in the world – SUD reprocessing and remanufacturing is governed by a completely different, and much more stringent, set of rules than those applied to reusable devices (premarket validation data

requirements with regard, at a minimum, to cleaning, sterilization and device performance). With its case material, MedTech is trying to mislead the reader.

Studies of hospital reuse of reusable devices are not relevant to hospital or commercial reprocessing or remanufacturing of SUDs. If anything, these studies may underscore the shortcomings of insufficiently validated OEM cleaning instructions for *reusable* devices. They suggest that perhaps OEMs of reusable devices should improve their premarket cleaning validations and instructions. They say nothing of independent cleaning validations of regulated reprocessors and remanufactures of SUDs.

Second, none of these studies evaluated EU MDR compliant reprocessed or remanufactured SUDs. Studies of *unregulated* reprocessed SUDs are also inapplicable to the current issue. Devices reprocessed by hospitals or by manufacturers that are not in compliance with EU MDR's requirements are now *unlawful*. To draw conclusions about a regulated commercial industry based upon the alleged non-compliant activities of hospitals is incontrovertibly misleading and thus provides an inappropriate standard of comparison.

None of the studies cited are relevant to, or representative of, the current standards in place for SUD reprocessing or remanufacturing. AMDR reaffirms its commitment to providing clinicians with the facts about reprocessed and remanufactured SUDs. As long as some OEMs continue to launch campaigns based on faulty, irrelevant or misleading studies, AMDR will act to provide complete and accurate information to providers and patients. The truth is that reprocessed and remanufactured SUDs allow hospital systems to save money, reduce their impact on the environment, and build supply chain resiliency all while continuing to provide the same high-quality care.

***Evidence from the US***

The concerns raised above, tantamount to baseless "what if" attacks, are in fact, not supported by the evidence where SUD reprocessing has been regulated for some time. The cleaning requirements imposed upon regulated SUD reprocessors and manufacturers are stringent, and, as a result, the final products are a safe and effective alternative to costly new devices. The US Government Accountability Office (GAO) issued a report in 2000 stating that FDA has "found no causal link between a reprocessed SUD and reported patient injury or death."[8] This was later reaffirmed in 2008, when a subsequent GAO report stated:

> "[N]one of the experts we interviewed cited the use of reprocessed single-use devices as a factor contributing to [Hospital Acquired Infections] in hospitals. Further, one of our recent reports found that available data, while limited, did not indicate that reprocessed single-use medical devices present elevated health risks to patients."[9]

***Informed Consent and Patient and Physician Transparency:***

Reprocessed and remanufactured SUDs compliant with the EU MDR are not investigational or experimental devices. Therefore, there is no legal, medical or ethical

basis for imposing a requirement to seek informed consent for the use of reprocessed or remanufactured devices but not for the use of original devices. SUD reprocessing is now regulated at the EU level. CE marked devices, whether new or remanufactured, definitively meet EU standards and the evidence provided indicates they do not present increased risks. There is no precedent for requiring informed consent for CE marked products. Further, the established Common Specifications explicitly do not require informed consent. MedTech has no legal or regulatory basis to make such a claim.

***Adverse Event reporting:***

The MedTech report asserts, without evidence, that safety issues with reprocessed SUDs might go unreported. There is no evidence given to support the claim that reprocessed SUD failures are erroneously reported to the OEM, or that infections resulting from reprocessed SUDs cannot be traced back to the reprocessor. This speculation is unfounded. The EU MDR and Common Specifications make clear that vigilance and reporting requirements fall to reprocessors and remanufacturers in the same way as they apply to any other OEM, and, like any other OEM, reprocessors must support and maintain their technical files based on such reporting and have it overseen and approved by Notified Bodies.

The reality in markets where SUD reprocessing has been regulated suggests just the opposite of what MedTech claims. First, FDA's medical device reporting requirements apply the same to OEMs and to reprocessors as it now does in Europe. This has now been the case for 20 years and FDA relies on this AND other voluntary reporting mechanisms to track for device errors causing harm or potential harm to patients.

Manufacturers, including SUD reprocessors, are required to report to FDA when they learn that their devices may have caused or contributed to a death or serious injury. Manufacturers and SUD reprocessors must also report to the FDA when their devices have malfunctioned and would be likely to cause or contribute to a serious injury or death if the malfunction were to recur. Hospitals are required to submit reports to FDA *and* the manufacturer when information reasonably suggests that a device has or may have caused or contributed to the death of a patient.

After over 20 years of regulated reprocessing at thousands of hospitals in the US, there is no data in FDA's database indicating an increased failure rate or harm to patients from reprocessed SUDs. In fact, the agency and the US Government Accountability Office (GAO) have concluded there is no link between reprocessed devices and an increased risk to patient safety:

> "After reviewing the available evidence – including FDA's process for identifying and investigating device-related adverse events reported to involve reprocessed SUDs, peer-reviewed studies published since 2000, and the results of our and FDA's consultations with hospital representatives – we found no reason to question FDA's analysis indicating that no causative link has been established between reported injuries or deaths and reprocessed SUDs." [10]

In addition, in the US, just as under the EU MDR, regulators have taken great pains to ensure that end-users (providers) know they are using a reprocessed or remanufactured SUDs so that users can report adverse events correctly. MedTech's allegations regarding underreporting or inaccurate reporting are not founded on any evidence. The US Federal Medical Device User Fee and Modernization Act (MDUFMA) of 2002 did what the EU MDR put in place just in 2017 – a requirement that reprocessed and remanufactured devices be clearly marked as such.[11]

Further, to date, AMDR is not aware of FDA or other regulatory authorities reporting evidence of erroneous filings where there have been mistakes regarding manufacturer versus reprocessor. No evidence has been presented by MedTech to back the claim that OEMs may be inappropriately identified as responsible parties rather than the relevant hospital or commercial SUD reprocessors. In AMDR's experience, this is another baseless OEM claim.

**About AMDR**

The Association of Medical Device Reprocessors is the global trade association for the regulated, professional single-use device reprocessing and remanufacturing industry. For 20 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 Innovative Health, Medline Renewal, NEScientific, ReNu Medical, 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 and lead the way for remanufacturing to play a defining role in the evolution and use of new device technologies.

**References:**

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[1] Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters, Schulte, Maga and Thonemann, *Sustainability*, January 2021.

[2] Transforming the Medical Device Industry: Road Map to a Circular Economy, MacNiell, Hopf, et. al., *Health Affairs*, December 2020; *See also*, Transforming the Medical Device Industry: Road Map to a Circular Economy, MacNiell, Hopf, et. al., *Health Affairs*, December 2020.

[3] Health Care Climate Footprint Report, *Health Care Without Harm* (accessed 1 February 2021).

[4] See, *supra*, note 2.

[5] Single-Use Medical Devices: Little Available Evidence of Harm from Reuse, but Oversight Warranted, U.S. Government Accountability Office, GAO/HEHS-00-123 (June 2000), at 11 [hereinafter 2000 GAO Report].

[6] See, *supra*, note 2.

[7] AMDR Bibliography of Peer-Reviewed Articles and Other Scientific Literature on Reprocessing, AMDR.

[8] 2000 GAO Report, *supra*, note 5.

[9] Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk, U.S. Government Accountability Office, GAO-08-147, (January 2008), at 1 (emphasis added) [hereinafter 2008 GAO Report].

[10] 2008 GAO Report, supra, note 9.

[11] MDUFMA requires that the labeling of reprocessed devices bear the reprocessor' s name and state that the device was reprocessed. 21 U.S.C. § 352(v), effective January 25, 2004. The law also requires that, in many instances, reprocessors include validation data in their premarket submissions. 21 U.S.C. § 360(o)(2)(B); see also 68 Fed. Reg. 38071 (June 26, 2003).