Europe's care in Europe's control: secure continuity of care through medical device reprocessing under the Medical Device Regulation

Single-use medical devices pose a huge risk for continuity of care in the EU

Your family member's surgery shouldn't depend on an oil tanker getting through the Strait of Hormuz. And yet it does [1]. Every year, billions of medical devices are shipped from all around the world to the EU. These devices are made from a wide range of materials, including critical raw materials [2] and crude oil-based polymers, that are subject to volatile availability and pricing. Empty supply cabinets in operating theaters and nursing wards across the EU are an increasingly realistic threat as trade wars, disease outbreaks, natural disasters and armed conflicts break global supply chains. When supply chains fail, patients pay the price through delayed diagnosis and treatment. In 2024, a hurricane flooding a single factory in North Carolina cut Dutch hospitals' supply of IV fluid bags by a quarter for months and forced nationwide rationing. Medical devices rely on similar fragile global supply chains.

We, as a coalition, want more reprocessable medical devices

A large share of medical devices, available on the current EU market, is designated for single-use under the Medical Device Regulation (MDR) [3]. This designation generally prevents reprocessing, meaning that devices are discarded and incinerated after one use. This results in the loss of valuable materials and resources. European healthcare institutions often have no choice but to purchase these single-use devices if no alternatives on the market exist. We want that to change. We want freedom of choice. Specifically, we want an EU market with safe reprocessable alternatives across device categories. That is, devices that after purchase can be locally cleaned, disinfected and/or sterilized to allow safe repeated use. Every device that can be safely reprocessed is one less device that needs to be sourced through fragile global supply chains. In the EU, we secure our gas pipelines and borders. It's time we secure the supply cabinets of our operating theaters and nursing wards as well.

Designing medical devices for single-use is a choice, and so is designing for reprocessing

Design choices that determine whether a medical device can be reprocessed are often made long before a device reaches the market. Manufacturers may choose materials, assemblies, electronic components or software architectures that *restrict* reprocessing. For example, devices may incorporate software-controlled components or electronic locking mechanisms that render the device unusable after a predefined number of uses, even where validated reprocessing procedures could restore device functionality and performance. Manufacturers may also make design choices that *enable* reprocessing. Examples of such design choices can be found across a broad range of medical categories, including for example laryngoscope blades [4], surgical staplers [5], surgical access devices (trocars) [6], surgical robotics [7] and medical imaging equipment [8]. These examples demonstrate that designing medical devices for single-use is a choice, and so is designing for reprocessing.

Medical devices, reprocessed through appropriate and validated procedures, are safe
Current evidence does not support claims that reprocessing of medical devices inherently compromises patient safety [3]. For example, a 2025 study covering more than 1.1 million cataract procedures over a nine-year period found no increase in infection rates associated with the reprocessing of phacoemulsification cassettes [9]. This evidence shows that such a successful outcome depends on the availability of validated reprocessing procedures and strict regulatory oversight.

Single-use medical devices should be the justified exception, not the default: our two asks
Given the above, we welcome the European Commission's proposal for Article 17 as part of the MDR revision [10]. This proposal has the potential to create a level playing field for all manufacturers and stimulate innovation in device categories where currently little to no reprocessable alternatives exist. Therefore, we urge the European Parliament – in particular the SANT Committee – and the Council of the European Union to:

1. **Keep intact the European Commission's requirement** that a single-use designation of medical devices should be duly justified by manufacturers.
2. **Set the evidentiary standard for justification of this single-use designation** by requiring manufacturers to provide objective and verifiable arguments that substantiate its necessity. This prevents a regulatory loophole whereby avoidable design choices themselves become sufficient justification.

For many device categories, justification of the single-use designation can be derived from existing knowledge, standards, guidance documents and state-of-the-art design practices rather than new full clinical investigations. This keeps the requirement proportionate yet robust.

A full-text proposal for the amendments can be found in ANNEX 1.

A list of all coalition partners is provided in ANNEX 2.

ANNEX 1 | Full text proposals

European Commission's proposal	Our coalition's proposal
1. A device shall only be intended for single-use where the manufacturer, in light of the design, construction, material, chemical, physical and biological properties of the device, cannot ensure that the device continues to meet the relevant safety and performance requirements when reused in accordance with its intended purpose after appropriate reprocessing. *The manufacturer's justification of an indication of single use shall be part of the technical documentation referred to in Annex II.*	*1. A device shall be designated for single use when the manufacturer demonstrates, on the basis of objective and verifiable evidence, that due to the intended purpose of the device and state-of-the-art options with respect to its design, construction, material, chemical, physical and biological characteristics, it cannot reasonably be reprocessed without compromising safety and performance requirements, even when appropriate and validated procedures are applied.* *Unchanged from European Commission's proposal*
2. If the device is not intended for single-use, the manufacturer shall provide information about the appropriate reprocessing process for allowing reuse in the instructions for use in accordance with Annex I, Section 23.4, point (n).	*Unchanged from European Commission's proposal*
3. Single-use devices and devices that cannot be further reprocessed may be subject to full refurbishing within the meaning of Article 2(31). The natural or legal person that carries out the full refurbishing shall be considered as the manufacturer of the fully refurbished device.	*Unchanged from European Commission's proposal*
4. The Commission may adopt, in accordance with Article 9(1), CS on general requirements regarding reprocessing of devices or fully refurbishing of single-use devices.	*4. The Commission may adopt, in accordance with Article 9(1), CS criteria and limitations for the qualification of devices as single use, including requirements related to intended purpose and design characteristics, as well as general requirements regarding the reprocessing of devices and the full refurbishing of single-use devices.*

References

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ANNEX 2 | Coalition partners

This statement is endorsed by the following coalition partners.

Coalition partner	Logo	Representative's name
Dutch Healthcare branch organisations (BoZ)		Coalition of UMCNL, NVZ, ActiZ, de Nederlandse ggz and VGN
University Medical Centers of the Netherlands (UCMNL)		Melanie Schmidt, director
Dutch Hospital Association (NVZ)		Veronique Esman-Peeters, director
Dutch Association for Residential and Home Care Organizations and Infant Health Clinics (ActiZ)		Wouter van Soest, director
Dutch Association of Mental Health and Addiction Care (de Nederlandse GGZ)		Jeroen Pepers, director
Dutch Association of Providers for Care to People with Disabilities (VGN)		Theo van Uum, director
Dutch Green Health Alliance (GZA)		Evelyn Brakema, Chair
MPZ – Environmental Platform for Healthcare		Adriaan van Engelen, Director
Health Care Without Harm Europe		Tatiana de Wée, circular programme manager