Medical device remanufacturing

# New markets for medical device remanufacturing across Europe

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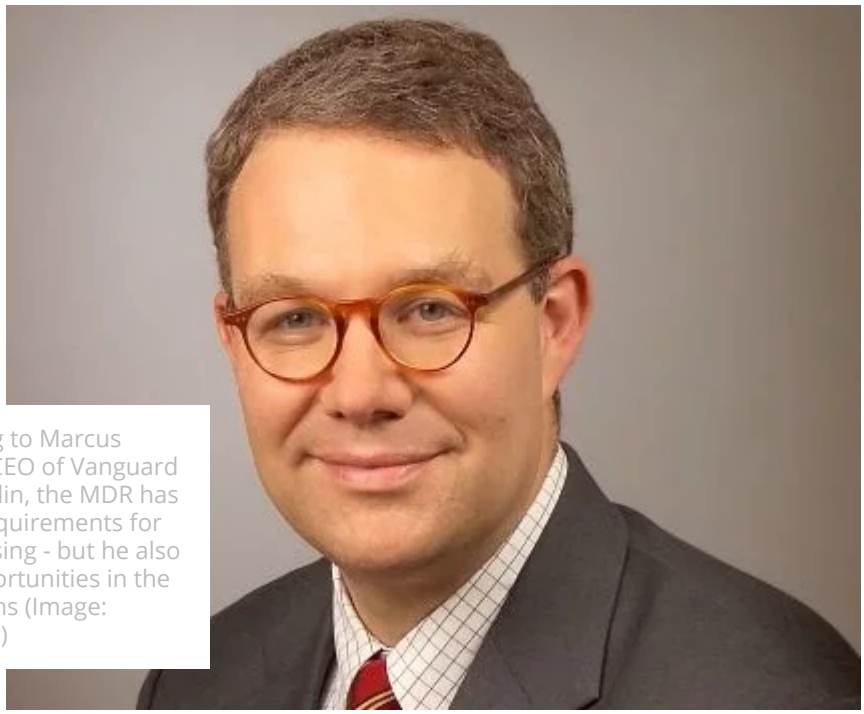

According to Marcus Bracklo, CEO of Vanguard AG in Berlin, the MDR has higher requirements for reprocessing - but he also sees opportunities in the regulations (Image: Vanguard)



**The company Vanguard specializes in the reprocessing of single-use medical devices, the medical remanufacturing. In an interview, CEO Marcus Bracklo reports that the topic of sustainability is now very popular with customers and**

**why his company is relaxed about the new European Regulation for Medical Devices (EU-MDR).**

*Tim Schröder*
*science journalist in Oldenburg*

**Mr. Bracklo, Vanguard AG has been reprocessing medical instruments for around 20 years. To what extent has remanufacturing changed?**

For one, **medical instruments** have become more complex, which makes **recovery** more challenging. Modern ablation catheters, for example, which are used to obliterate muscle tissue in cardiac arrhythmias, have narrow lumens through which coolant is passed. For remanufacturing, we need **special machines** for reliable **cleaning** and **disinfection of** such instruments , which we have developed ourselves because cleaning with commercially available systems does not work. At the moment there is a completely different development. The aspect of sustainability is becoming increasingly important for our customers, the hospitals. Recovered products are not only significantly cheaper than the new product, the**Carbon footprint** is also dramatically lower. While the issue of **cost-** effectiveness has so far played a decisive role for the clinics, we now hear more and more often that customers attach importance to conserving resources.

**And is there any noticeable effect?**

We had the Fraunhofer-Gesellschaft investigate how big the **CO2 savings** are. The emissions from restored products are around **50 percent** lower. That is significant. This sustainability aspect, combined with the significant savings of up to 50 percent, has now also induced the state's National Health Services in **Great Britain** to increasingly rely on restored products in the future. We are currently **expanding** the **National Health Services medical remanufacturing program** significantly.

**Doesn't the new European regulation for medical devices, the MDR, prevent this cooperation?**

On the contrary, the **MDR** creates a uniform **set of rules for the medical remanufacturing** of single-use products **for the** first time . The rules of the MDR enable the **circular economy for single-use medical products across the EU** according to a uniform CE certification. We then have a kind of European approval.

**On the other hand, you have the same warranty obligations as the manufacturer of the product. Many consider this to be over-regulation.**

I think it is right that the **remanufacturing business** which **product liability** takes over. However, some of the requirements for CE marking are excessive. For

example, we have to use reverse engineering to create component plans and technical drawings - for a product that already exists. This causes avoidable additional costs. According to Articles 17 III and IV of the MDR, however, the nation **states** can also allow articles to be placed on the market that meet the so-called **common specifications of the EU** - essential medical and technical requirements. These regulations are more geared towards the special situation of medical remanufacturing.

**So the MDR is not a stumbling block?**

No, it opens up new markets for us. In the past ten years, the USA and Germany were the only countries in the world with regulations for the reprocessing of single-use products. Other countries could not benefit from the advantages of the **circular economy** . The **EU-wide regulation** now gives us markets in other countries.

**Still, the MDR increases the effort required to approve restored articles.**

Naturally. But we have already prepared for it in recent years. Around half of our portfolio now has a CE mark. We will certify the other part in Germany, our largest market, according to the new common specifications. For older items that we would have taken out of the range in the medium term anyway, it is not worth the cost of CE or CS approval. All in all, we see more advantages than disadvantages in the MDR.

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## More about reprocessing:

https://medizin-und-technik.industrie.de/technik/entwicklung/ re-preparation-von-medizinprodukte-was- geht-und-erlaubt-ist/