Rethink
Remanufacture

Henry Kuper, RN CNRA

Business Development Manager

18-04-2023

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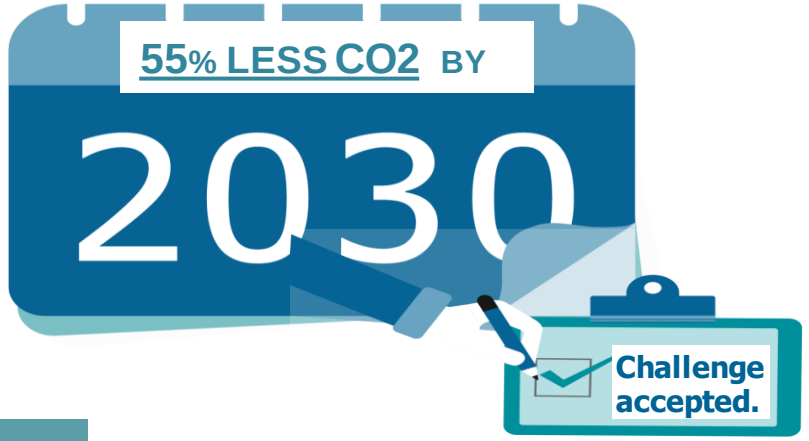
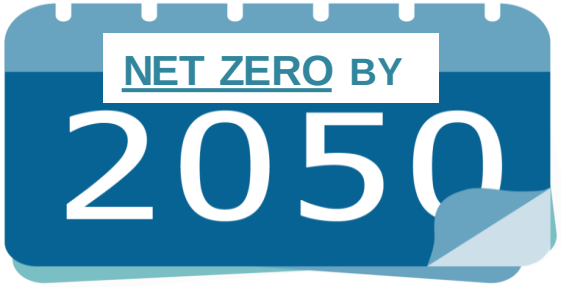
Invitational `Innovatie door Inspiratie`. Van der Valk Hotel Utrecht.

Green Deal



Contribution & Collaboration!



Green Deal Zorg 3.0 - Vergroen de zorg

Zorginstellingen en ziekenhuizen willen mensen gezond houden en beter maken. Dat vraagt ook om een schoon milieu

& Vermindering van vervuiling en verspilling in de zorg

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Ministry of Health, Welfare and Sport

Regelgeving die beter aansluit bij medische ontwikkelingen !

MDR Verordening (EU) 2017/745 medische hulpmiddelen

sinds 26 mei 2022

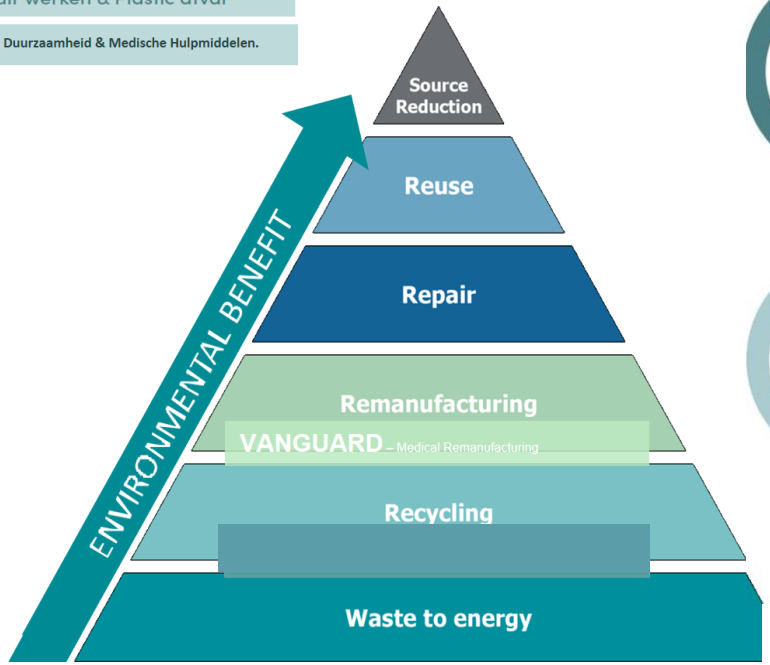
Deze EU-wetgeving regelt een verbeterde patiëntveiligheid en klinische veiligheid van hulpmiddelen. Ook sluit deze wetgeving beter aan bij technische innovaties en ontwikkelingen in de medische wetenschap.

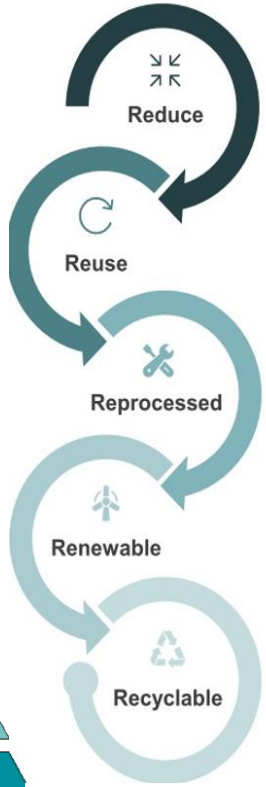
Regulation aims to ensure the smooth functioning of the internal market as regards medical devices as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises high standards of quality and safety

Remanufacturing superior to recycling

Circulair werken & Plastic afval

Platform Duurzaamheid & Medische Hulpmiddelen.





1. Reduce: Can you do without the product?

2. Reuse: Can you buy reusable products instead of single use?

3. (Buy) Reprocessed: Can you buy reprocessed or refurbished?

4. (Buy) Renewable: What is the product made of?

5. (Buy) Recyclable: Is the product recyclable?

Remanufacturing is an common-process in the USA, Canada, Israel, Japan.

- 25 years Worldwide experience present & expanding with EU Law now allowing this too.
- Fully regulated.

On 26-05-**2021**, **EUROPE allowed** *Remanufacturing*. Article 17 EU MDR 2017/745 in force!

OPT IN : **Now Legal regulated in**

UK

Netherlands

Belgium

Germany

Ireland

Croatia

Sweden

Spain

Source: https://health.ec.europa.eu/medical-devices-topics-interest/reprocessing-medical-devices/national-rules-reprocessing-single-use-devices_en

- Only CE-certified European Medical Remanufacturer. (**Berlin**)
- **+ 25 years**, Vanguard global medical remanufacturing sets a standard, empowering healthcare institutions operating more sustainable in a future-oriented manner.
- Vanguard belongs to the Santo Holding AG –healthcare group with 1,5 bn. € in equity and 500 m. sales – owned by Strüngmann. (founders of Hexal)

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- **Medical remanufacturing**:

enables hospitals to optimize the supply chain ecologically and economically **without compromising safety and quality!**

Sustainable

We extend the product life cycle of medical devices and enable a more sustainable future for the medical technology sector. Breathing new life into single-use medical devices, we combat climate change and protect our planet's resources.

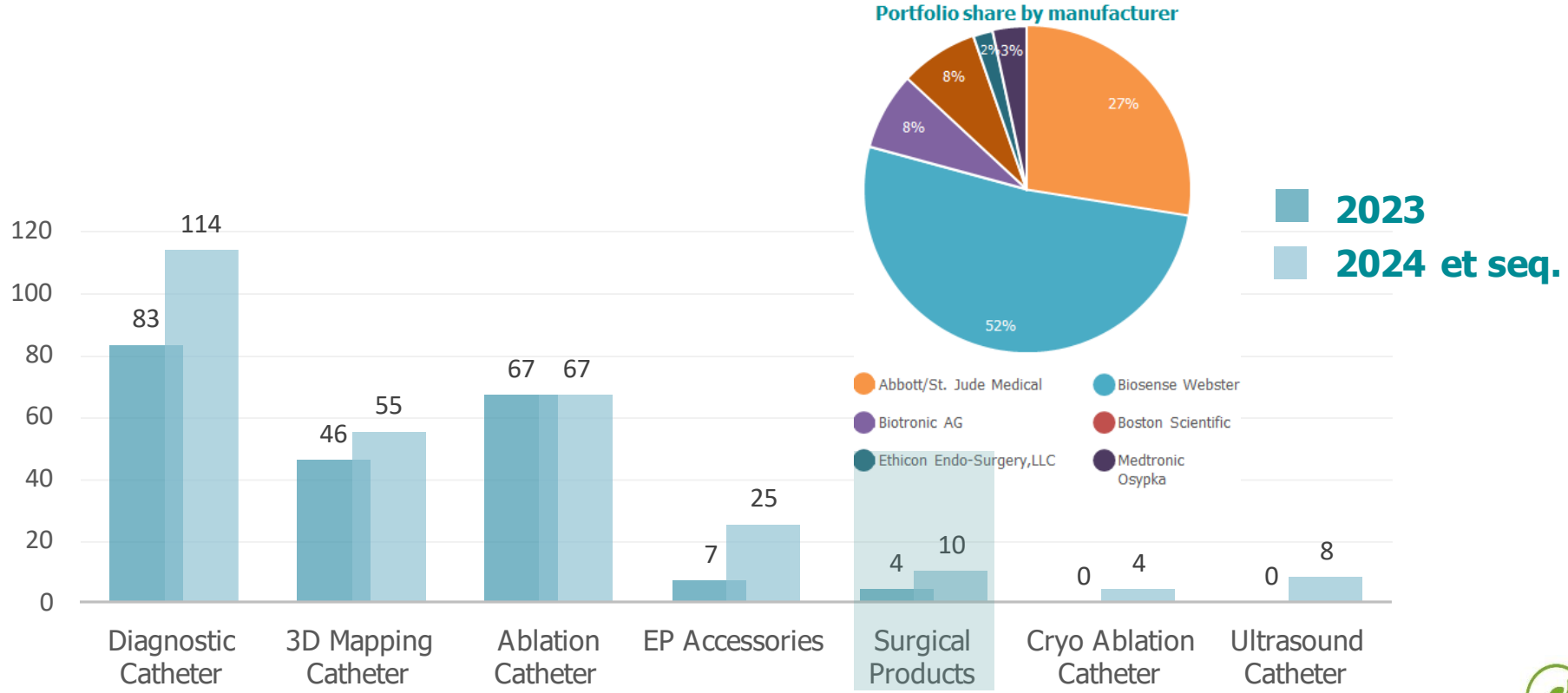
Safe

Using certified, state-of-the-art processes, we set the global standard in medical remanufacturing. We guarantee that our remanufactured products are restored to their original safety and effectiveness and fully comply with all EU regulatory requirements.

Economical

Through medical remanufacturing, the pursuit of sustainability pays off. There are no additional costs involved; in fact, medical remanufacturing can result in cost savings of up to 50 per cent.

CE Portfolio Development Plan Status 2023 vs. 2024 et seq.



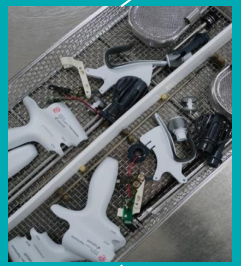
VANGUARD
MEDICAL REMANUFACTURING

What´s the **difference?**

Safe
Made with original parts CE marked

NOT cost effective
Full price item

NOT sustainable
Adds to medical waste



Safe
Made with original parts CE marked

Cost effective
50% of the cost of the original

Sustainable
Reduces carbon footprint, abiotic resource use and medical waste

OEM | **Vanguard**

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Our products are subjected to over 20 individual tests. These include:

Unique rinsing concept
Potential residue is flushed from the lumen using a specially-developed cleaning system. Cleaning media that flow through the lumen are subject to continuous volumetric monitoring.

Visual inspection
We inspect the device at up to 40x magnification, checking for any changes in its curvature shape or damage along the full length of the catheter from the electrical connection to the tip.

Mechanical function test
We test the performance of each component. In the case of force-sensing catheters, our processes ensure full functionality.

Vanguard Product Verification (VPV)
Testing of the entire electrical functionality such as insulation, continuity, capacitance and the temperature sensors by a specially developed testing system

Microbiological Testing
To confirm the effectiveness of the cleaning process, each catheter is checked for possible protein residues in our L2-hygiene Vanguard laboratory using the modified OPA method (in accordance with ISO 15883).

VANGUARD
MEDICAL REMANUFACTURING

The circular economy must not stop at the gates of the healthcare system.

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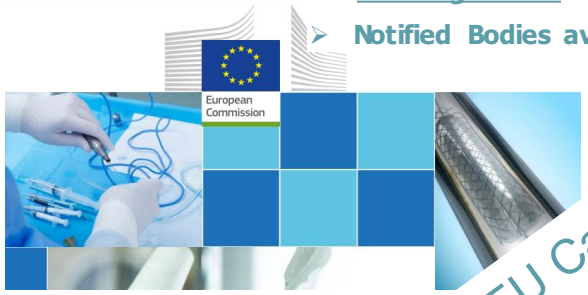
VANGUARD
MEDICAL REMANUFACTURING

Challenge nr. I:

➢ **Notified Bodies availability** development *slows approval process & implementation* ***remanufactured CE-certified products***!



Brussels, 8 March 2023

From: General Secretariat of the Council

To: Council

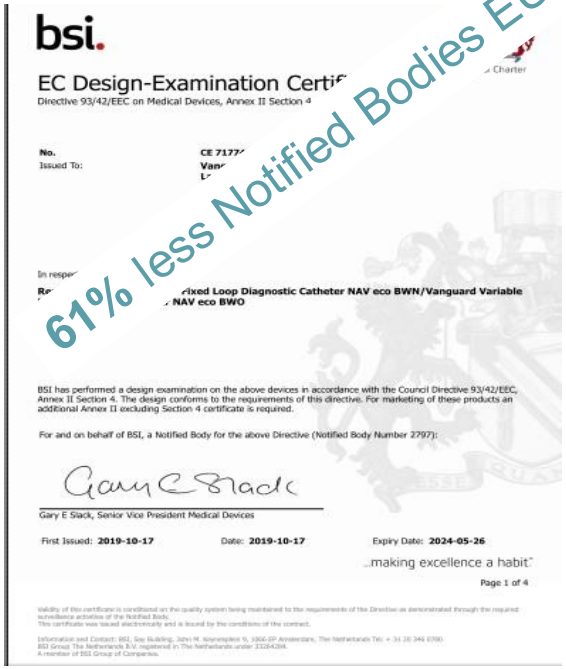
Implementation of the Medical Device Regulations

- Information from the Commission

- **Gaining momentum in designation of notified bodies**

Continued implementation of actions to enhance notified body capacity and ensure availability of medical devices and in vitro diagnostics

61% less Notified Bodies EU Capacity


bsi.

EC Design-Examination Certi

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. CE 7177

Issued To: Vas

In respe

Re ixed Loop Diagnostic Catheter NAV eco BWN/Vanguard Variable NAV eco BWO

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: 2019-10-17 Date: 2019-10-17 Expiry Date: 2024-05-26

...making excellence a habit.

Page 1 of 4

How has Notified Body capacity been impacted by the MDR?

Before the enactment of the EU MDR, there were around 96 certified Notified Bodies who were able to perform conformity assessments under the Medical Device Directive MDD 93/42/EC.

What are EU MDR Notified Bodies?

EU MDR Notified Bodies are organisations who have been designated by the EU Member State to assess medical devices and associated technical documents for conformity with the requirements of the Medical Device Regulation (EU) 2017/745.

As of December 2022, current statistics show that there are 37 MDR certified Notified Bodies fully approved under the MDR.

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Challenge nr. II:

- **Environment (regional)** *transport regulation implementation differences regarding identified to be remanufactured CE-products*!

Rijkswaterstaat
Ministerie van Infrastructuur en Waterstaat

Afval Circulair

Kenniscentrum Circulaire Economie

Eural
Handreiking EURAL

Augustus 2019

Deze handreiking is bedoeld voor degenen die zich van afval ontdoen, en daarnaast voor afvalinzamelaars en -verwerkers. De **ontdoener** van een afvalstof is verplicht om de juiste Euralcode voor het afval vast te stellen voordat hij zich van deze stof ontdoet. Tot slot kan ook het bevoegd gezag bij handhaving en vergunning-verlening deze handreiking gebruiken om de juistheid van een Euralcode te toetsen.

1-4

Wet milieubeheer, artikelen 10.37, 10.45 en 10.48.
wetten.nl - Regeling - Wet milieubeheer - BWBR0003245 (overheid.nl)

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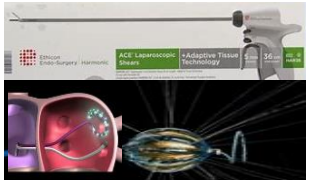
Safe 1

Sustainable 2



3 **Economical**

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TOGETHER WE CAN

55% LESS CO2

2030

NET ZERO

2050

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Landelijk Netwerk de Groene OK

Hoe kunnen wij u helpen?

- → Anesthesiedampen & Medicijnresten
- → Circulair werken & Plastic afval
- → Energie
- → Landelijke leidraad duurzaamheid

Thank you for your attention!

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