

EU Declaration of Conformity

Clean 'n Easy Cleaning Family

Manufacturer: Wecovi BV
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Ch. of Commerce: 050 50253
VAT: NL800601622B01

Trade mark: Wecoline®
SRN number: NL-MF-000004371

Basic-UDI Product: **872029945250203613MW**

UDI-DI	Reference	Description
8720299452541	02036130	Clean 'n Easy Interior, roll of 150 cloth
8720299452558	02036134	Clean 'n Easy Hygienic, roll of 150 cloth

Intended Use: Cleaning of non-invasive medical devices and other hard surfaces in healthcare facilities, nursing homes, retirement homes etcetera.

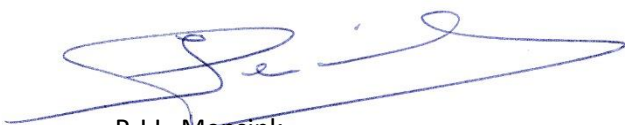
Risk Class: The medical devices are classed I under 745/2017 MDR Annex VIII. Referring to 5.2 of Annex IX of the Medical Device Regulation 2017/745, the products of the Clean 'n Easy cleaning Family are:

- Not Pharmaceutical, nor contain Pharmaceutical ingredients.
- The product is not used on humans or as an invasive device.
- Specials rules do not apply (also not rule 16).

Declaration: This declaration of conformity is issued under the sole responsibility of Wecovi BV. The medical devices of the Wecoline Clean 'n Easy cleaning Family, described in this declaration are in conformity with the (EU) Regulation 745/2017 MDR

Regulations and guidances: 745/2017 Medical Device regulation
NEN-EN-ISO13485:2016 Medical devices, QM systems
EN-ISO-14971:2019 Risk Management
NEN-EN-ISO 15223:2021 Symbols to be used with Medical Device labels.
A.I.S.E. / IHO Guidelines on the regulation (EU) 2017/745 on medical devices
CEN_ISO_TR_24971:2020 Guidance on the application of ISO14971
648/2004 Detergents regulation
1272/2008 CLP regulation
1907/2006 REACH regulation

Zwolle, 10-3-2023

A handwritten signature in blue ink, appearing to read "P.J.L. Mensink".

P.J.L. Mensink
Quality Manager