

EC Declaration of Conformity

Manufacturers Name ME Medical AG
Manufacturers Address via Valresa 52C, 6645 Brione s. Minusio, Switzerland
Authorized Representative: Axel Madsen Health Care A/S
Name:

Authorized Representative Gøngehusvej 252 • 2950 Vedbæk • Denmark
Address:

| <u>Name of Devices and Product code:</u> | <u>Basic UDI-DI:</u> |
|---|----------------------|
| Ref. BEC-5000001 BeCare Professional Clipper with Charger (STRZYGARKA, ŁADOWARKA BECARE, KOMPLET) | 5 902729 053686 |
| Ref. BEC-5000012 BeCare Clipper Universal Blade (OSTRZE STANDARDOWE DO STRZYGARKI BECARE) | 5 902729 053761 |
| Ref. BEC-5000012 BeCare Clipper Neuro Blade (OSTRZE NEURO DO STRZYGARKI BECARE) | 5 902729 053792 |

UMDNS-Code: 16-580 shaver, skin preparation

Classification: Class I according to annex VIII of direct. (EU) MDR 2017/745

Conformity assessment ME Medical AG uses the following procedures for the CE-labeling of their
Route: products according the Regulation MDR 2017/745, IEC 60601-1:2005, AMD1:2012

This declaration of conformity is issued under the sole responsibility of ME Medical AG. We hereby declare that the medical devices specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by Bureaux Veritas. All supporting documentation is retained at the premises of the manufacturer and authorized EU representative.

This Declaration is valid until 31 December 2024



Urs Eisenring, Director

Brione s. Minusio, 26.05.2021