

## EC Declaration of Conformity

Manufacturers Name                      ME Medical AG  
Manufacturers Address                    via Valresa 52C, 6645 Brione s. Minusio, Switzerland  
Authorized Representative:  
Name:    Axel Madsen Health Care A/S  
Authorized Representative                Gøngehusvej 252 • 2950 Vedbæk • Denmark  
Address:

<u>Name of Devices and Product code:</u>	<u>Basic UDI-DI:</u>
Ref. BEC-500001 BeCare Professional Clipper with Charger (STRZYGARKA, ŁADOWARKA BECARE, KOMPLET)	5 902729 053686
Ref. BEC-500012 BeCare Clipper Universal Blade (OSTRZE STANDARDOWE DO STRZYGARKI BECARE)	5 902729 053761
Ref. BEC-500012 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  
Route:                                        ME Medical AG uses the following procedures for the CE-labeling of their  
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