

B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

DECLARATION OF CONFORMITY

Product Category: Physically acting medical devices for Multi-Drug-Resistant-Organism decolonization for topical and oral application

Product (Name, Type)	Size	Date of CE marking/ Batch No.	Remarks
Prontoderm® Solution	500 ml	09.11.2009 / 9461M05	
	5 l	15.06.2010 / 0242M06	
Prontoderm® Foam	200 ml	03.12.2009 / 9494M14	
Prontoderm® Nasal Gel	30 ml	26.05.2010 / 0213M04	
ProntOral®	250 ml	11.12.2009 / 9505M17	
Prontoderm® Wipes	10 Tissues	26.10.2010 / 0053M03	

Article numbers: see attachment

Conformity Assessment Procedure	acc. to ANNEX II of the COUNCIL DIRECTIVE 93/42/EEC
Classification	according to ANNEX IX of the COUNCIL DIRECTIVE 93/42/EEC
Class / Rule	Class III / Rule 1, 4, 5 and 13
Applied Standards	EN ISO 13485:2016, Certificate No. Q5 061585 0030
CE Certificate	No. 2113812CE02, valid until May 26, 2024
EC Certificates	No. 2113812DE03, valid until May 26, 2024
Notified Body	DEKRA Certification B.V., Meander 1051, 6825 MJ Arnhem, The Netherlands
Identification no.	0344
EC REP	B. Braun Melsungen AG, Carl-Braun-Strasse 1, 34212 Melsungen, Germany

We herewith declare under our sole responsibility that the above mentioned products meet all the provisions of the COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC, which apply to them, as stated in ANNEX II.

Sempach, 13.04.2021

B. Braun Medical AG


Peter Egli
Head of Quality Management
CoE Infection Prevention & Renal Fluids


Dr. Michael Gluschke
Director Global Regulatory Affairs
CoE Infection Prevention & Renal Fluids

DECLARATION OF CONFORMITY
Attachment for Medical Devices Class III

Art. No.	Product Name	Remarks
400102	Prontoderm® Solution (500 ml)	
400121	Prontoderm® Solution (500 ml)	
400100	Prontoderm® Solution (5 l)	
400111	Prontoderm® Foam (200 ml)	
400128	Prontoderm® Foam (200 ml)	
400200	Prontoderm® Nasal Gel (30 ml)	
400220	Prontoderm® Nasal Gel (30 ml)	
400221	Prontoderm® Nasal Gel (30 ml)	
400700	ProntOral® (250 ml)	
400730	ProntOral® (250 ml)	
400731	ProntOral® (250 ml)	
400106	Prontoderm® Wipes (10 tissues)	