

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

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

<b>Art. No.</b>	<b>Product Name</b>	<b>Remarks</b>
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)	