

B. Braun Medical AG  
Seesatz 17  
6204 Sempach  
Switzerland

## DECLARATION OF CONFORMITY

**Product Category:** Medical Devices for Wound Bed Preparation

Product (Name, Type)	Size	Date of CE marking / Batch No.	Remarks
Prontosan® Wound Irrigation Solution	40 ml	09.05.2009 / 9192M15	
	350 ml	02.03.2009 / 9075M21	
	1000 ml	22.08.2011 / 11453M04	
Prontosan® Wound Gel	30 ml	20.02.2009 / 9082M03	
Prontosan® Wound Gel X	50 g	08.06.2012 / 12235M14	
	250 g	08.04.2011 / 0345M23	
Prontosan® acute Wound Gel	30 g	19.01.2012 / 12061M03	
Prontosan® Wound Spray	75 ml	15.03.2012 / 12122M09	

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 4 and 13
<b>Applied Standards</b>	EN ISO 13485:2016, Certificate No. Q5 061585 0030
<b>CE Certificate</b>	No. 2113812CE01, valid until May 26, 2024
<b>EC Certificates</b>	No. 2113812DE01, No. 2113812DE02, No. 2113812DE04, No. 2113812DE05, all valid until May 26, 2024 No. 2113812DE06, valid until March 1, 2023
<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, 07.06.2021

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>
400484	Prontosan® Wound Irrigation Solution (24 x 40 ml)	
400487	Prontosan® Wound Irrigation Solution (24 x 40 ml)	
400455	Prontosan® Wound Solution (24 x 40 ml)	
400403	Prontosan® Wound Irrigation Solution (10 x 350 ml)	
400415	Prontosan® Wound Irrigation Solution (10 x 350 ml)	
400416	Prontosan® Wound Irrigation Solution (10 x 350 ml)	
400493	Prontosan® Wound Irrigation Solution (10 x 350 ml)	
400417	Prontosan® Wound Irrigation Solution (350 ml)	
400423	Prontosan® Wound Irrigation Solution (350 ml)	
400452	Prontosan® Wound Solution (350 ml)	
400446	Prontosan® Wound Irrigation Solution (10 x 1000 ml)	
400494	Prontosan® Wound Irrigation Solution (10 x 1000 ml)	
400465	Prontosan® Wound Solution (1000 ml)	
400505	Prontosan® Wound Gel (30 ml)	
400515	Prontosan® Wound Gel (30 ml)	
400516	Prontosan® Wound Gel (30 ml)	
400595	Prontosan® Wound Gel (30 ml)	
400517	Prontosan® Wound Gel X (50 g)	
400531	Prontosan® Wound Gel X (50 g)	
400508	Prontosan® Wound Gel X (250 g)	
400532	Prontosan® Wound Gel X (250 g)	
400511	Prontosan® acute Wound Gel (30 g)	
400512	Prontosan® acute Wound Gel (30 g)	
400521	Prontosan® acute Wound Gel (30 g)	
400563	Prontosan® Wound Spray (75 ml)	PLM Name: Viscoplast Preparat to oczyszczania ran
400565	Prontosan® Wound Spray (75 ml)	
400566	Prontosan® Wound Spray (75 ml)	
400567	Prontosan® Wound Spray (75 ml)	
400568	Prontosan® Wound Spray (75 ml)	