

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

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 4 and 13
Applied Standards	EN ISO 13485:2016, Certificate No. Q5 061585 0030
CE Certificate	No. 2113812CE01, valid until May 26, 2024
EC Certificates	No. 2113812DE01, No. 2113812DE02, No. 2113812DE04, No. 2113812DE05, all valid until May 26, 2024 No. 2113812DE06, valid until March 1, 2023
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, 21.06.2021

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

Effective

DECLARATION OF CONFORMITY
Attachment for Medical Devices Class III

Art. No.	Product Name	Remarks
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 End of Life; TW 216624, 30.09.2022
400565	Prontosan® Wound Spray (75 ml)	
400566	Prontosan® Wound Spray (75 ml)	
400567	Prontosan® Wound Spray (75 ml)	
400568	Prontosan® Wound Spray (75 ml)	