B BRAUN

SHARING EXPERTISE

B Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

DECLARATION OF CONFORMITY

Product Category: Sterile pads for wound debridement

Product (Name, Type)	**Date of CE marking & Batch No.**	**Unit**	**Art. No.**	**Last batch manufactured in acc. with COUNCIL DIRECTIVE 93/42/EEC**
Prontosan® Debridement Pad	20.12.2016 17134M26	3 x 1 piece	3908456	21142M01
	20.12.2016 17144M19	10 x 1 piece	3908457	21131M04

Conformity Assessment Procedure	according to ANNEX V of the COUNCIL DIRECTIVE 93/42/EEC
Classification	according to ANNEX IX of the COUNCIL DIRECTIVE 93/42/EEC
Class / Rule	Class Is / Rule 4
Applied Standards **EC Certificate**	EN ISO 13485:2016, Certificate No. Q5 061585 0030 No. G2S 061585 0035 Rev. 00, valid until 26 May, 2024
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany
Identification no.	0123
EC REP	B. Braun Melsungen AG, Carl-Braun-Strasse 1, 34212 Melsungen, Germany

We herewith declare under our sole responsibility that the above mentioned product meets 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 it, as stated in ANNEX V.

Sempach, 05.07.2021

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