

Number: 2247049TD03

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Manufacturer:

B.Braun Medical AG

Seesatz 17

CH-6204 Sempach

Switzerland

SRN ID.: CH-MF-000017781

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

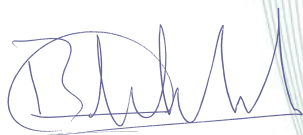
0344

Supplement to certificate: 2113812CN

Authorized Representative: B. Braun Melsungen AG, Carl-Braun-Straße 1, 34212 Melsungen, Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Principal Certification Manager

First Issued: **6 October 2023**

Date: **29 November 2023**

Expiry date: **1 October 2028**

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s):

Class III	
Basic UDI-ID: 40392390000009232Q Device Name: Prontosan Wound Gel X Type: M040405 Hydrogel Dressings Models: <ul style="list-style-type: none">- PWX_50- PWX_250	<i>Intended Purpose:</i> For cleansing, moistening and decontamination of acute, chronic and infected dermal wounds and burns.

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	6-10-2023	2113812CN25	First issue
1	29-11-2023	2113812CN26	Revised

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