Konformitätserklärung
Declaration of Conformity

Wir | We

B. Braun Medical AG
Seesatz 17
CH-6204 Sempach
Schweiz / Switzerland
SRN: CH-MF-000017781

EU/EC REP:
B. Braun Melsungen AG
Carl-Braun-Strasse 1
DE-34212 Melsungen
Deutschland / Germany
SRN: DE-AR-000000202

erklären in eigener Verantwortung,
dass das Produkt

hereby declare in our own responsibility
that the product

Prontosan® Debridement Pad
Pad zum Wund Debridement
Basis-UDI-DI: 4039239000000065ZQ
(Artikelnummern siehe Anlage I)

Prontosan® Debridement Pad
Wound debridement pad
Basic-UDI-DI: 4039239000000065ZQ
(article numbers see attachment I)

Erste Charge produziert nach MDR 2017/745:
Charge: 21411M07

First Batch manufactured acc. MDR 2017/745
Batch-No.: 21411M07

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 übereinstimmt

is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745

Konformitätsbewertungsverfahren
nach Anhang IX
nach Anhängen II & III
der oben genannten Verordnung

Conformity Assessment Procedure
according to annex IX
according to annexes II & III
of the Regulation named above

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse I steril

Classification
according to annex VIII of the Regulation named above
Class I sterile

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Effective

Des weiteren erklären wir in eigener Verantwortung, dass oben genanntes Medizinprodukt die Anforderung zu folgender EU Verordnung / Richtlinie
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
erfüllt / erfüllen

Gültig bis
Gemäss gültigem EC Zertifikat
G11 061585 0037 Rev. 00
Gültig bis: 2026-03-14

Furthermore, we declare in our own responsibility that the above-mentioned medical device meet the requirements of the following EU Regulation or Directive
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
fulfil

Valid until
according to our valid EC Certificate
G11 061585 0037 Rev. 00
Valid until: 2026-03-14

Anlage I /Attachment I

MEDIZINPRODUKTE Klasse Is / MEDICAL DEVICES Class Is

Product name	Art. No	UDI-DI	Basic UDI-DI	First manuf. Batch acc. MDR 2017/745
Prontosan® Debridement Pad (3 Pads)	3908456	7612449149757	4039239000000065ZQ	21411M07
Prontosan® Debridement Pad (10 Pads)	3908457	7612449149801	4039239000000065ZQ	21491M01

Title: Declaration of Conformity - Prontosan Debridement Pad MDR Initiator: Andrea ? Wassmer

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Wassmer, Andrea (buchanch)
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Meaning: Document signed as Author
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UserName: Egli, Peter (eglipech)
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Date: Monday, 21 February 2022, 07:51 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Gluschke, Michael (glusmich)
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Date: Wednesday, 23 February 2022, 12:14 W. Europe Daylight Time
Meaning: Approve Document
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