

**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 Produkthereby declare in our own responsibility
that the product**Prontosan® Debridement Pad**Pad zum Wund Debridement
Basis-UDI-DI: 403923900000065ZQ
(Artikelnummern siehe Anlage I)**Prontosan® Debridement Pad**Wound debridement pad
Basic-UDI-DI: 403923900000065ZQ
(article numbers see attachment I)Erste Charge produziert nach MDR 2017/745:
Charge: 21411M07First Batch manufactured acc. MDR 2017/745
Batch-No.: 21411M07**Prontosan® Wound Irrigation Solution Adapter**Sterile non-active transfer devices for irrigation
solution medical devices
Basis-UDI-DI: 403923900000066ZS
(Artikelnummern siehe Anlage I)**Prontosan® Wound Irrigation Solution Adapter**Sterile non-active transfer devices for irrigation
solution medical devices
Basic-UDI-DI: 403923900000066ZS
(Article numbers see attachment I)Erste Charge produziert nach MDR 2017/745:
Charge: 22493M21First Batch manufactured acc. MDR 2017/745
Batch-No.: 22493M21**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

Classification

according to annex VIII of the Regulation named above

Klasse I steril

Class I sterile

Benannte StelleTÜV SÜD Product Service GmbH
Kennnummer 0123**Notified Body**TÜV SÜD Product Service GmbH
Identification number 0123**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****Furthermore, we declare in our own responsibility
that the above-mentioned medical device meets
the requirements of the following EU Regulation or**REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND
OF THE COUNCIL**fulfil****Gültig bis**Gemäss gültigem EC Zertifikat
G11 061585 0037 Rev. 01
Gültig bis: 2026-03-14**Valid until**according to our valid EC Certificate
G11 061585 0037 Rev. 01
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
Prontosan® Wound Irrigation Solution Adapter (10 Adapter & 10 Prontosan Wound Irrigation Solution 1000mL)	3908437	7612449140358	4039239000000066ZS	22493M21

HISTORY OF DOCUMENT

Version	Modification
01	New document according to MDR
02	Adding first MDR Batch
03	Adding the product "Prontosan Wound Irrigation Solution Adapter"
04	Adding the UDI-DI and First manuf. Batch number for product "Prontosan Wound Irrigation Solution Adapter"
05	Correction of EC certificate number, Correction of manufacturing batch number for "Prontosan Wound Irrigation Solution Adapter", Correction of "Prontosan Wound Irrigation Solution Adapter" description under product name

Title: Declaration of Conformity - Classification Is MDR Initiator: Laura ? Idorasi

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

UserName: Idorasi, Laura (idorlaro)
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UserName: Gluschke, Michael (glusmich)
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Meaning: Approve Document
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