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

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

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

Prontosan® Wound Irrigation Solution Adapter
Sterile non-active transfer devices for irrigation solution medical devices
Basis-UDI-DI: 4039239000000066ZS
(Artikelnummern siehe Anlage I)

Erste Charge produziert nach MDR 2017/745:
Charge: 22493M21

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

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung

hereby declare in our own responsibility that the product

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

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

Prontosan® Wound Irrigation Solution Adapter
Sterile non-active transfer devices for irrigation solution medical devices
Basic-UDI-DI: 4039239000000066ZS
(Article numbers see attachment I)

First Batch manufactured acc. MDR 2017/745
Batch-No.: 22493M21

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

Classification
according to annex VIII of the Regulation named above

Effective

Klasse I steril

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 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

Gültig bis
Gemäss gültigem EC Zertifikat
G11 061585 0037 Rev. 01
Gültig bis: 2026-03-14

Class I sterile

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

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. 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
06	Correction of manufacturing batch number for “Prontosan Wound Irrigation Solution Adapter”
07	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)
Title: Head of regulatory Affairs
Date: Friday, 12 January 2024, 08:22 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Egli, Peter (eglipech)
Title: OM-QM-CH05 - Head of Quality Management
Date: Thursday, 18 January 2024, 12:13 W. Europe Daylight Time
Meaning: Approve Document
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