

Wir

We

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SRN: CH-MF-000017781

erklären, dass die EU Konformitätserklärung ist erstellt in
eigener Verantwortung, des Herstellers**Prontosan® Wound Irrigation Solution**Wound Bed Preparation
Basis-UDI-DI: 4039239000009242S
(Artikelnummern siehe Anlage I)**Prontosan® Wound Gel**Wound Bed Preparation
Basis-UDI-DI: 4039239000009222N
(Artikelnummern siehe Anlage I)**Prontosan® Wound Gel X**Wound Bed Preparation
Basis-UDI-DI: 4039239000009232Q
(Artikelnummern siehe Anlage I)**Prontosan® Wound Spray**Wound Bed Preparation
Basis-UDI-DI: 4039239000009252U
(Artikelnummern siehe Anlage I)**Prontosan® acute Wound Gel**Wound Bed Preparation
Basis-UDI-DI: 4039239000009212L
(Artikelnummern siehe Anlage I)mit den Anforderungen der Medizinprodukte Verordnung
(EU) 2017/745 übereinstimmen**Konformitätsbewertungsverfahren**nach Anhang IX der oben
genannten Verordnungthe EU declaration of conformity is issued under the sole
responsibility of the manufacturer**Prontosan® Wound Irrigation Solution**Wound Bed Preparation
Basic-UDI-DI: 4039239000009242S
(Article number see attachment I)**Prontosan® Wound Gel**Wound Bed Preparation
Basic-UDI-DI: 4039239000009222N
(Article number see attachment I)**Prontosan® Wound Gel X**Wound Bed Preparation
Basic-UDI-DI: 4039239000009232Q
(Article number see attachment I)**Prontosan® Wound Spray**Wound Bed Preparation
Basic-UDI-DI: 4039239000009252U
(Article number see attachment I)**Prontosan® acute Wound Gel**Wound Bed Preparation
Basic-UDI-DI: 4039239000009212L
(Article number see attachment I)are in conformity with the requirements of the Medical
Device Regulation (EU) 2017/745**Conformity Assessment Procedure**according to annex IX of the
Regulation named above

Klassifizierung
gemäß Anhang VIII
der oben genannten Verordnung
Klasse III

Benannte Stelle
DEKRA Certification B. V.
Kennnummer 0344

Gültig bis
gemäss gültigem EC Zertifikat
Prontosan Wound Irrigation Solution:
2247049TD01 gültig bis 01.10.2028
Prontosan Wound Gel:
2247049TD02 gültig bis 01.10.2028
Prontosan Wound Gel X:
2247049TD03 gültig bis 01.10.2028
Prontosan Wound Spray:
2247049TD04 gültig bis 01.08.2029
Prontosan acute Wound Gel:
2247049TD05 gültig bis 01.09.2029
Prontosan EU Qualitätsmanagement Zertifikat
2247049CE01 gültig bis 01.10.2028

Classification
according to annex VIII
of the Regulation named above
Class III

Notified Body
DEKRA Certification B. V.
Identification number 0344

Valid until
according to our valid EC Certificate
Prontosan Wound Irrigation Solution:
2247049TD01 valid until 01.10.2028
Prontosan Wound Gel:
2247049TD02 valid until 01.10.2028
Prontosan Wound Gel X:
2247049TD03 valid until 01.10.2028
Prontosan Wound Spray:
2247049TD04 valid until 01.08.2029
Prontosan acute Wound Gel:
2247049TD05 valid until 01.09.2029
Prontosan EU Quality Management Certificate
2247049CE01 valid until 01.10.2028

Anlage I / Attachment I

| Produktname | Model | Art. Nr. | UDI-DI | Basis UDI-DI |
|---|----------|----------|---------------|-------------------|
| Product name | Model | Art. No | UDI-DI | Basic UDI-DI |
| Prontosan® Wound Irrigation Solution (24 x 40 ml) | PWS_40 | 400484 | 4046964041501 | 4039239000009242S |
| Prontosan® Wound Irrigation Solution (24 x 40 ml) | PWS_40 | 400487 | 4046955163786 | 4039239000009242S |
| Prontosan® Wound Solution (24 x 40 ml) | PWS_40 | 400455 | 4046964948527 | 4039239000009242S |
| Prontosan® Wound Irrigation Solution (6 x 40 ml) | PWS_40 | 400419 | 4046963759216 | 4039239000009242S |
| Prontosan® Wound Irrigation Solution (350 ml) | PWS_350 | 400403 | 4039239517955 | 4039239000009242S |
| Prontosan® Wound Irrigation Solution (350 ml) | PWS_350 | 400415 | 4039239541271 | 4039239000009242S |
| Prontosan® Wound Irrigation Solution (350 ml) | PWS_350 | 400416 | 4039239541301 | 4039239000009242S |
| Prontosan® Wound Irrigation Solution (350 ml) | PWS_350 | 400417 | 4046963112035 | 4039239000009242S |
| Prontosan® Wound Irrigation Solution (350 ml) | PWS_350 | 400423 | 4046963787271 | 4039239000009242S |
| Prontosan® Wound Irrigation Solution (350 ml) | PWS_350 | 400431 | 4046963759247 | 4039239000009242S |
| Prontosan® Wound Solution (350 ml) | PWS_350 | 400452 | 4046964948558 | 4039239000009242S |
| Prontosan® Wound Irrigation Solution (1000 ml) | PWS_1000 | 400446 | 7612449130953 | 4039239000009242S |
| Prontosan® Wound Solution (1000 ml) | PWS_1000 | 400465 | 4046964948589 | 4039239000009242S |
| Prontosan® Wound Irrigation Solution (1000 ml) | PWS_1000 | 400432 | 4046964087097 | 4039239000009242S |
| Prontosan® Wound Gel (30 ml) | PWG_30 | 400505 | 4039239517993 | 4039239000009222N |
| Prontosan® Wound Gel (30 ml) | PWG_30 | 400515 | 4039239541332 | 4039239000009222N |
| Prontosan® Wound Gel (30 ml) | PWG_30 | 400516 | 4039239541363 | 4039239000009222N |
| Prontosan® Wound Gel (30 ml) | PWG_30 | 400595 | 4046964948282 | 4039239000009222N |
| Prontosan® Wound Gel (30 ml) | PWG_30 | 400510 | 4046963759193 | 4039239000009222N |
| Prontosan® Wound Gel X (50 g) | PWX_50 | 400517 | 4046964093425 | 4039239000009232Q |
| Prontosan® Wound Gel X (50 g) | PWX_50 | 400531 | 4046964948671 | 4039239000009232Q |
| Prontosan® Wound Gel X (50 g) | PWX_50 | 400523 | 4046964761652 | 4039239000009232Q |
| Prontosan® Wound Gel X (250 g) | PWX_250 | 400508 | 4046963840174 | 4039239000009232Q |
| Prontosan® Wound Gel X (250 g) | PWX_250 | 400532 | 4046964949067 | 4039239000009232Q |
| Prontosan Wound Spray (75ml) | PSY_75 | 400565 | 7612449130908 | 4039239000009252U |
| Prontosan Wound Spray (75ml) | PSY_75 | 400566 | 7612449135552 | 4039239000009252U |
| Prontosan Wound Spray (75ml) | PSY_75 | 400567 | 7612449140457 | 4039239000009252U |
| Prontosan Wound Spray (75ml) | PSY_75 | 400568 | 7612449140501 | 4039239000009252U |
| Prontosan acute Wound Gel (30gr) | PaWG_30 | 400511 | 7612449130854 | 4039239000009212L |

| Produktname | Model | Art. Nr. | UDI-DI | Basis UDI-DI |
|----------------------------------|---------|----------|---------------|-------------------|
| Product name | Model | Art. No | UDI-DI | Basic UDI-DI |
| Prontosan acute Wound Gel (30gr) | PaWG_30 | 400512 | 7612449132209 | 4039239000009212L |
| Prontosan acute Wound Gel (30gr) | PaWG_30 | 400521 | 7612449144752 | 4039239000009212L |

HISTORY OF DOCUMENT

| Version | Modification |
|----------------|---|
| 01 | New document acc. Regulation (EU) 2017/745 |
| 02 | Typo correction in "Switzerland" Removal of "10x" from Prontosan Wound Irrigation Solution Product Name as this is not the smallest sellable unit Correction of UDI for Art Nr. 400484 from 4046964041396 to 4046964041501 as 24x40ml is the smallest sellable unit Correction of UDI for Art Nr. 400419 from 4046964103575 to 4046963759216 as 6x40ml is the smallest sellable unit |
| 03 | Addition of EU QM Certificate |
| 04 | Addition of Prontosan Wound Spray & Prontosan acute Wound Gel |
| 05 | Error correction, certificate number and expiration not stated for Prontosan Wound Spray and Prontosan acute Wound Gel |
| 06 | EOL Article 400572 Prontosan Wound Spray according TW 374117 |
| 07 | EOL Article 400573 Prontosan acute Wound Gel according TW 372320 |

Title: Declaration of Conformity MDR Prontosan Family Initiator: Jan-Aurel ? Pfister

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

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