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- Declaration of Conformity -
Declaration of Conformity MDR
Prontosan Family

B. Braun Medical AG
Infection Control - Regulatory Affairs
Medical Devices

Effective

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Page: 1 of 6

Wir

We

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Schweiz / Switzerland

EU/EC REP
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Carl-Braun-Strasse 1
34212 Melsungen
Deutschland / Germany

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: 40392390000009242S
(Artikelnummern siehe Anlage I)

Prontosan® Wound Gel
Wound Bed Preparation
Basis-UDI-DI: 40392390000009222N
(Artikelnummern siehe Anlage I)

Prontosan® Wound Gel X
Wound Bed Preparation
Basis-UDI-DI: 40392390000009232Q
(Artikelnummern siehe Anlage I)

Prontosan® Wound Spray
Wound Bed Preparation
Basis-UDI-DI: 40392390000009252U
(Artikelnummern siehe Anlage I)

Prontosan® acute Wound Gel
Wound Bed Preparation
Basis-UDI-DI: 40392390000009212L
(Artikelnummern siehe Anlage I)

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

Konformitätsbewertungsverfahren
nach Anhang IX der oben
genannten Verordnung

the EU declaration of conformity is issued under the sole
responsibility of the manufacturer

Prontosan® Wound Irrigation Solution
Wound Bed Preparation
Basic-UDI-DI: 40392390000009242S
(Article number see attachment I)

Prontosan® Wound Gel
Wound Bed Preparation
Basic-UDI-DI: 40392390000009222N
(Article number see attachment I)

Prontosan® Wound Gel X
Wound Bed Preparation
Basic-UDI-DI: 40392390000009232Q
(Article number see attachment I)

Prontosan® Wound Spray
Wound Bed Preparation
Basic-UDI-DI: 40392390000009252U
(Article number see attachment I)

Prontosan® acute Wound Gel
Wound Bed Preparation
Basic-UDI-DI: 40392390000009212L
(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

Effective

Klassifizierung

gemäß Anhang VIII
der oben genannten Verordnung
Klasse III

Benannte Stelle

DEKRA Certification B. V.
Kennnummer 0344

Gültig bis

gemäß gültigem EC Zertifikat
Pronotosan 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
Pronotosan 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	40392390000009242S
Prontosan® Wound Irrigation Solution (24 x 40 ml)	PWS_40	400487	4046955163786	40392390000009242S
Prontosan® Wound Solution (24 x 40 ml)	PWS_40	400455	4046964948527	40392390000009242S
Prontosan® Wound Irrigation Solution (6 x 40 ml)	PWS_40	400419	4046963759216	40392390000009242S
Prontosan® Wound Irrigation Solution (350 ml)	PWS_350	400403	4039239517955	40392390000009242S
Prontosan® Wound Irrigation Solution (350 ml)	PWS_350	400415	4039239541271	40392390000009242S
Prontosan® Wound Irrigation Solution (350 ml)	PWS_350	400416	4039239541301	40392390000009242S
Prontosan® Wound Irrigation Solution (350 ml)	PWS_350	400417	4046963112035	40392390000009242S
Prontosan® Wound Irrigation Solution (350 ml)	PWS_350	400423	4046963787271	40392390000009242S
Prontosan® Wound Irrigation Solution (350 ml)	PWS_350	400431	4046963759247	40392390000009242S
Prontosan® Wound Solution (350 ml)	PWS_350	400452	4046964948558	40392390000009242S
Prontosan® Wound Irrigation Solution (1000 ml)	PWS_1000	400446	7612449130953	40392390000009242S
Prontosan® Wound Solution (1000 ml)	PWS_1000	400465	4046964948589	40392390000009242S
Prontosan® Wound Irrigation Solution (1000 ml)	PWS_1000	400432	4046964087097	40392390000009242S
Prontosan® Wound Gel (30 ml)	PWG_30	400505	4039239517993	40392390000009222N
Prontosan® Wound Gel (30 ml)	PWG_30	400515	4039239541332	40392390000009222N
Prontosan® Wound Gel (30 ml)	PWG_30	400516	4039239541363	40392390000009222N
Prontosan® Wound Gel (30 ml)	PWG_30	400595	4046964948282	40392390000009222N
Prontosan® Wound Gel (30 ml)	PWG_30	400510	4046963759193	40392390000009222N
Prontosan® Wound Gel X (50 g)	PWX_50	400517	4046964093425	40392390000009232Q
Prontosan® Wound Gel X (50 g)	PWX_50	400531	4046964948671	40392390000009232Q
Prontosan® Wound Gel X (50 g)	PWX_50	400523	4046964761652	40392390000009232Q
Prontosan® Wound Gel X (250 g)	PWX_250	400508	4046963840174	40392390000009232Q
Prontosan® Wound Gel X (250 g)	PWX_250	400532	4046964949067	40392390000009232Q
Prontosan Wound Spray (75ml)	PSY_75	400565	7612449130908	40392390000009252U
Prontosan Wound Spray (75ml)	PSY_75	400566	7612449135552	40392390000009252U
Prontosan Wound Spray (75ml)	PSY_75	400567	7612449140457	40392390000009252U
Prontosan Wound Spray (75ml)	PSY_75	400568	7612449140501	40392390000009252U
Prontosan acute Wound Gel (30gr)	PaWG_30	400511	7612449130854	40392390000009212L

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	40392390000009212L
Prontosan acute Wound Gel (30gr)	PaWG_30	400521	7612449144752	40392390000009212L
Prontosan acute Wound Gel (30gr)	PaWG_30	400573	4046955744305	40392390000009212L

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

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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