

Wir

We

**B. Braun Medical AG  
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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: 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:  
XYZ gültig bis XYZ  
Prontosan acute Wound Gel:  
XYZ gültig bis XYZ  
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:  
XYZ valid until XYZ  
Prontosan acute Wound Gel:  
XYZ valid until XYZ  
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 Wound Spray (75ml)	PSY_75	400572	4046955744343	40392390000009252U

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	400511	7612449130854	4039239000009212L
Prontosan acute Wound Gel (30gr)	PaWG_30	400512	7612449132209	4039239000009212L
Prontosan acute Wound Gel (30gr)	PaWG_30	400521	7612449144752	4039239000009212L
Prontosan acute Wound Gel (30gr)	PaWG_30	400573	4046955744305	4039239000009212L

**HISTORY OF DOCUMENT**

<b>Version</b>	<b>Modification</b>
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

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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Meaning: Approve Document  
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