

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)

mit den Anforderungen der Medizinprodukte Verordnung
(EU) 2017/745 übereinstimmen**Konformitätsbewertungsverfahren**nach Anhang IX der oben
genannten Verordnung**Klassifizierung**gemäß Anhang VIII
der oben genannten Verordnung
Klasse III**Benannte Stelle**DEKRA Certification B. V.
Kennnummer 0344the 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)

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**Classification**according to annex VIII
of the Regulation named above
Class III**Notified Body**DEKRA Certification B. V.
Identification number 0344**Effective**

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 EU Qualitätsmanagement Zertifikat

2247049CE01 gültig bis 01.10.2028

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 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

HISTORY OF DOCUMENT

<u>Version</u>	<u>Modification</u>
<u>01</u>	<u>New document acc. Regulation (EU) 2017/745</u>
<u>02</u>	<u>Typo correction in "Switzerland"</u> <u>Removal of "10x" from Prontosan Wound Irrigation Solution Product Name as this is not the smallest sellable unit</u> <u>Correction of UDI for Art Nr. 400484 from 4046964041396 to 4046964041501 as 24x40ml is the smallest sellable unit</u> <u>Correction of UDI for Art Nr. 400419 from 4046964103575 to 4046963759216 as 6x40ml is the smallest sellable unit</u>
<u>03</u>	<u>Addition of EU QM Certificate</u>

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:

UserName: Pfister, Jan-Aurel (pfisjach)
Title: Regulatory Affairs Manager
Date: Thursday, 18 July 2024, 11:50 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Gluschke, Michael (glusmich)
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Date: Thursday, 18 July 2024, 16:13 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Egli, Peter (eglipech)
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Date: Friday, 19 July 2024, 07:51 W. Europe Daylight Time
Meaning: Approve Document
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Effective