

Konformitätserklärung
Declaration of Conformity

Wir

We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germanyerklären in eigener Verantwortung,
dass das/die Produkt/ehereby declare in our own responsibility
that the product/s**Aqua B. Braun**
Sterile Water for Irrigation
NaCl 0.9% B. Braun
Sodium Chloride 0.9% for Irrigation
Solución para Irrigación Vitulia NaCl 0,9%
0,9% w/v Sodium Chloride Irrigation Solution**Aqua B. Braun**
Sterile Water for Irrigation
NaCl 0.9% B. Braun
Sodium Chloride 0.9% for Irrigation
Solución para Irrigación Vitulia NaCl 0,9%
0,9% w/v Sodium Chloride Irrigation Solution**Ringer B. Braun**
Ringer-Lactate B. Braun
Glucose 5% B. Braun
der Produktgruppe Spüllösungen zur topischen,
intra- und postoperativen Verwendung
(Artikelnummern siehe Anlage I)**Ringer B. Braun**
Ringer-Lactate B. Braun
Glucose 5% B. Braun
of the Product Group Solutions for Irrigation for
Topical, Intra- and Postoperative use
(article numbers see attachment I)mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

is/are in compliance with the following directive

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte,
geändert durch Richtlinie 2007/47/EGCouncil Directive 93/42/EEC of 14 June 1993
concerning Medical Devices,
amended by Directive 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie**Conformity assessment procedure**
according to annex II (excluding section 4)
of the Directive named above**Klassifizierung**
gemäß Anhang IX der oben genannten Richtlinie:**Classification**
according to annex IX of the Directive named
above:
Class IIa

Klasse IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Notified body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Datum der ersten CE-Kennzeichnung**
2003-06**Date of first CE-marking**
2003-06

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Document-No.: **TD-004**
Revision-No.: **19**
Effective Date: **Last date of signature**
Page: **2 of 5**

Effective

Gültig bis
2024-05-26

Valid until
2024-05-26

Effective

Konformitätserklärung
Declaration of Conformity**Anlage I / Attachment I**

Art.-Nr. / Art. No.	Produktname / Product Name	Klasse / Class
0065729E	Aqua B. Braun	IIa
0066571E	Aqua B. Braun	IIa
0069415E	Aqua B. Braun	IIa
0082423E	Aqua B. Braun	IIa
0082479E	Aqua B. Braun	IIa
3521380	Sterile Water for Irrigation	IIa
3521390	Sterile Water for Irrigation	IIa
3553949	Aqua B. Braun	IIa
3553957	Aqua B. Braun	IIa
3570910	Aqua B. Braun	IIa
387872	Aqua B. Braun	IIa
387873	Aqua B. Braun	IIa
387874	Aqua B. Braun	IIa
387875	Aqua B. Braun	IIa
442464	Aqua B. Braun	IIa
442465	Aqua B. Braun	IIa
442466	Aqua B. Braun	IIa
442467	Aqua B. Braun	IIa
FREU812	Aqua B. Braun	IIa
FREU852	Aqua B. Braun	IIa
FREU912	Aqua B. Braun	IIa
FREU932	Aqua B. Braun	IIa
E30275	Sterile Water for Irrigation	IIa
E30277	Sterile Water for Irrigation	IIa
E70275	Sterile Water for Irrigation	IIa
E70277	Sterile Water for Irrigation	IIa
EB7277	Water for Irrigation	IIa
0066569E	NaCl 0,9% B. Braun	IIa
0066570E	NaCl 0,9% B. Braun	IIa
0069414E	NaCl 0,9% B. Braun	IIa
3521360	Sodium Chloride 0.9% for Irrigation	IIa
3521370	Sodium Chloride 0,9% for Irrigation	IIa
3570100	NaCl 0.9% B. Braun	IIa
3570110	NaCl 0.9% B. Braun	IIa
3570120	NaCl 0.9% B. Braun	IIa
3570130	NaCl 0.9% B. Braun	IIa
3570140	NaCl 0.9% B. Braun	IIa
3570150	NaCl 0.9% B. Braun	IIa
3570160	NaCl 0.9% B. Braun	IIa

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3570170	NaCl 0.9% B. Braun	IIa
3570300	NaCl 0.9% B. Braun	IIa
3570301	Sodium Chloride 0,9% for Irrigation	IIa
3570310	NaCl 0.9% B. Braun	IIa
3570330	NaCl 0,9% B. Braun	IIa
3570340	NaCl 0.9% B. Braun	IIa
3570350	NaCl 0.9% B. Braun	IIa
3570360	NaCl 0,9% B. Braun	IIa
3570370	NaCl 0.9% B. Braun	IIa
3570380	NaCl 0.9% B. Braun	IIa
3570390	NaCl 0,9% B. Braun	IIa
3570410	NaCl 0.9% B. Braun	IIa
3570420	NaCl 0.9% B. Braun	IIa
3570440	NaCl 0.9% B. Braun	IIa
3570450	NaCl 0.9% B. Braun	IIa
3570460	Estericlean NaCl 0,9%	IIa
3570470	NaCl 0.9% B. Braun	IIa
3570480	NaCl 0.9% B. Braun	IIa
3570900	NaCl 0,9% B. Braun	IIa
3637006	Sodium Chloride 0,9% for Irrigation	IIa
3637010	Sodium Chloride 0,9%	IIa
391858	NaCl 0,9% B. Braun	IIa
391859	NaCl 0,9% B. Braun	IIa
391860	NaCl 0,9% B. Braun	IIa
391861	NaCl 0,9% B. Braun	IIa
450268	Solución para Irrigación Vitulia NaCl 0,9%	IIa
450272	Solución para Irrigación Vitulia NaCl 0,9%	IIa
E32275	0,9% w/v Sodium Chloride Irrigation Solution	IIa
E70375	0.9% w/v Sodium Chloride Irrigation Solution	IIa
E70377	0.9% w/v Sodium Chloride Irrigation Solution	IIa
E70477	0,9% w/v Sodium Chloride Irrigation Solution	IIa
FREU850	NaCl 0,9% B. Braun	IIa
FREU910	NaCl 0.9% B. Braun	IIa
FREU930	NaCl 0.9% B. Braun	IIa
FREU950	NaCl 0.9% B. Braun	IIa
FREU970	NaCl 0.9% B. Braun	IIa
FREU916	Glucose 5% B. Braun	IIa
3570000	Ringer B. Braun	IIa
3570010	Ringer B. Braun	IIa
3570020	Ringer B. Braun	IIa
3570030	Ringer B. Braun	IIa

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3570040	Ringer B. Braun	IIa
3570050	Ringer B. Braun	IIa
3570060	Ringer B. Braun	IIa
FREU864	Ringer B. Braun	IIa
FREU924	Ringer B. Braun	IIa
FREU944	Ringer B. Braun	IIa
FREU964	Ringer B. Braun	IIa
FREU984	Ringer B. Braun	IIa
3570490	Ringer-Lactate B. Braun	IIa
3570500	Ringer-Lactate B. Braun	IIa
3570510	Ringer-Lactate B. Braun	IIa
3570520	Ringer-Lactate B. Braun	IIa
3570530	Ringer-Lactate B. Braun	IIa
FREU920	Ringer-Lactate B. Braun	IIa

Effective

Title: td-004-declaration-of-conformity Initiator: Alain ? Bordon

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

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Title: HC-RA-CH01-Global-Regulatory-Affairs
Date: Thursday, 27 February 2020, 13:54 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Weis, Harald (weishade)
Title: HC-RA-DE08P VP Global RA
Date: Thursday, 27 February 2020, 18:23 W. Europe Daylight Time
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UserName: Ritz, Frank (ritzfrde)
Title: HC-QM DE08 Head QM CoE Pharmaceuticals
Date: Friday, 28 February 2020, 07:56 W. Europe Daylight Time
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UserName: Labeirie, Eva (labeevch)
Title: HC-RA-CH01-Global-Regulatory-Affairs-Manager
Date: Friday, 28 February 2020, 09:56 W. Europe Daylight Time
Meaning: Approve Document

Dichiarazione di conformità

Noi

B.Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germania

con la presente, dichiariamo sotto la nostra responsabilità che i/il prodotto/i

Aqua B. Braun
Sterile Water for Irrigation
NaCl 0.9% B. Braun
Sodium Chloride 0.9% for Irrigation
Solución para Irrigación Vitulia NaCl 0,9%
0,9% w/v Sodium Chloride Irrigation Solution

Ringer B. Braun
Ringer-Lactate B. Braun
Glucose 5% B. Braun

della famiglia di prodotto delle soluzioni per irrigazione per uso topico, intra e post-operatorio
(per gli articoli vedere l'allegato I)

è/sono in conformità con la seguente Direttiva

Direttiva del Consiglio 93/42/CEE del 14 giugno 1993 riguardante i dispositivi medici
emendata dalla Direttiva 2007/47/CE

Procedura di valutazione della conformità
secondo gli allegati II (escludendo la sezione 4) della Direttiva sopra citata

Classificazione
secondo l'allegato IX della Direttiva sopra nominata
Classe IIa

Organismo Notificato
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Monaco
Germania
Numero identificativo 0123

Data del primo marchio CE
06-2003

Valida fino a
26-05-2024

Dichiarazione di conformità

ALLEGATO 1

No Articolo	Nome prodotto	Classe
0065729E	Aqua B. Braun	IIa
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FREU920	Ringer-Lactate B. Braun	IIa