

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

Konformitätserklärung
Declaration of Conformity

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 ConformityRevision-No.: **19**Effective Date: **Last date of signature**Page: **3 of 5****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 |

Konformitätserklärung
Declaration of ConformityRevision-No.: **19**Effective Date: **Last date of signature**Page: **4 of 5**

| | | |
|---------|--|-----|
| 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 |

Konformitätserklärung
Declaration of Conformity

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

| | | |
|---------|-------------------------|-----|
| 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:

UserName: Bordon, Alain (bordalch)
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
Meaning: Approve Document

UserName: Ritz, Frank (ritzfrde)
Title: HC-QM DE08 Head QM CoE Pharmaceuticals
Date: Friday, 28 February 2020, 07:56 W. Europe Daylight Time
Meaning: Approve Document

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 |
| 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 |

Dichiarazione di conformità

| | | |
|---------|--|-----|
| 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 |

Dichiarazione di conformità

| | | |
|---------|-------------------------|-----|
| 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 |