

Konformitätserklärung**Declaration of Conformity**

Wir

We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

erklären in eigener Verantwortung,
dass das/die Produkt/e

hereby declare in our own responsibility
that the product/s

Aqua B. Braun

Aqua Purificata

Sterile Water for Irrigation

Gedestilleerd water

NaCl 0.9% B. Braun

Sodium Chloride 0.9% for Irrigation

Natriumchloride 0,9%

Solución para Irrigación Vitulia NaCl 0,9%

0,9% w/v Sodium Chloride Irrigation Solution

Isotonische Natriumchlorid-Lösung ad us. vet. B. Braun

Vet Care

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

der Produktgruppe Spüllösungen zur topischen,

intra- und postoperativen Verwendung

(Artikelnummern siehe Anlage I)

Aqua B. Braun
Aqua Purificata
Sterile Water for Irrigation
Gedestilleerd water
NaCl 0.9% B. Braun
Sodium Chloride 0.9% for Irrigation
Natriumchloride 0,9%
Solución para Irrigación Vitulia NaCl 0,9%
0,9% w/v Sodium Chloride Irrigation Solution
Isotonische Natriumchlorid-Lösung ad us. vet. B. Braun
Vet Care

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/EG

Council 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:

Klasse IIa

Classification
according to annex IX of the Directive named
above:
Class IIa

Benannte Stelle

TÜV SÜD Product Service GmbH

Ridlerstraße 65

80339 München

Deutschland

Notified body

TÜV SÜD Product Service GmbH

Ridlerstraße 65

80339 München

Germany

Melsungen, 2016-06-10

Melsungen

i. V.

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Dr. F. Ritz

Vice President Quality Management Pharma Hospital Care Division

Harald Weis

Vice President Global Regulatory Affairs CoE Pharmaceuticals

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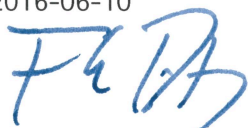
Kennnummer 0123

Identification number 0123

Datum der ersten CE-Kennzeichnung
2003-06**Date of first CE-marking**
2003-06**Gültig bis**
2021-06-10**Valid until**
2021-06-10

Melsungen, 2016-06-10

i. V.



Dr. F. Ritz

Vice President Quality Management Pharma Hospital Care Division

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Harald Weis

Vice President Global Regulatory Affairs CoE Pharmaceuticals

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 |
| 0082540E | Aqua B. Braun | IIa |
| 0086647F | Aqua Purificata | 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 |
| 3624331 | Gedestilleerd water | IIa |
| 3624404 | Gedestilleerd water | IIa |
| 3624409 | Gedestilleerd water | 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 |
| FR99852 | 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 |
| 0066569E | NaCl 0,9% B. Braun | IIa |
| 0066570E | NaCl 0,9% B. Braun | IIa |
| 0069414E | NaCl 0,9% B. Braun | IIa |
| 0081645E | NaCl 0,9% B. Braun | IIa |
| 3521360 | Sodium Chloride 0.9% for Irrigation | IIa |
| 3521370 | Sodium Chloride 0,9% for Irrigation | IIa |

Konformitätserklärung**Declaration of Conformity**

| | | |
|---------|---|-----|
| 3570100 | NaCl 0.9% B. Braun | Ila |
| 3570110 | NaCl 0.9% B. Braun | Ila |
| 3570120 | NaCl 0.9% B. Braun | Ila |
| 3570130 | NaCl 0.9% B. Braun | Ila |
| 3570140 | NaCl 0.9% B. Braun | Ila |
| 3570150 | NaCl 0.9% B. Braun | Ila |
| 3570160 | NaCl 0.9% B. Braun | Ila |
| 3570170 | NaCl 0.9% B. Braun | Ila |
| 3570210 | NaCl 0.9% B. Braun | Ila |
| 3570300 | NaCl 0.9% B. Braun | Ila |
| 3570301 | Sodium Chloride 0,9% for Irrigation | Ila |
| 3570310 | NaCl 0.9% B. Braun | Ila |
| 3570330 | NaCl 0,9% B. Braun | Ila |
| 3570340 | NaCl 0.9% B. Braun | Ila |
| 3570350 | NaCl 0.9% B. Braun | Ila |
| 3570360 | NaCl 0,9% B. Braun | Ila |
| 3570370 | NaCl 0.9% B. Braun | Ila |
| 3570380 | NaCl 0.9% B. Braun | Ila |
| 3570390 | NaCl 0,9% B. Braun | Ila |
| 3570410 | NaCl 0.9% B. Braun | Ila |
| 3570420 | NaCl 0.9% B. Braun | Ila |
| 3570440 | NaCl 0.9% B. Braun | Ila |
| 3570450 | NaCl 0.9% B. Braun | Ila |
| 3570470 | NaCl 0.9% B. Braun | Ila |
| 3570480 | NaCl 0.9% B. Braun | Ila |
| 3570900 | NaCl 0,9% B. Braun | Ila |
| 3623015 | Natriumchloride 0,9% | Ila |
| 391858 | NaCl 0,9% B. Braun | Ila |
| 391859 | NaCl 0,9% B. Braun | Ila |
| 391860 | NaCl 0,9% B. Braun | Ila |
| 391861 | NaCl 0,9% B. Braun | Ila |
| 450268 | Solución para Irrigación Vitulia NaCl 0,9% | Ila |
| 450272 | Solución para Irrigación Vitulia NaCl 0,9% | Ila |
| E32275 | 0,9% w/v Sodium Chloride Irrigation Solution | Ila |
| E70375 | 0.9% w/v Sodium Chloride Irrigation Solution | Ila |
| E70377 | 0.9% w/v Sodium Chloride Irrigation Solution | Ila |
| E70477 | 0,9% w/v Sodium Chloride Irrigation Solution | Ila |
| FREU850 | NaCl 0,9% B. Braun | Ila |
| FREU910 | NaCl 0.9% B. Braun | Ila |
| FREU930 | NaCl 0.9% B. Braun | Ila |
| FREU950 | NaCl 0.9% B. Braun | Ila |
| FREU970 | NaCl 0.9% B. Braun | Ila |
| FV17107 | Isotonische Natriumchlorid-Lösung ad us. vet. B. Braun Vet Care | Ila |

**Konformitätserklärung
Declaration of Conformity**Document-No.: **TD-004**Revision-No.: **15**Effective Date: **Last date of
signature**Page: **5 of 5**

| | | |
|---------|-------------------------|-----|
| FREU916 | Glucose 5% B. Braun | Ila |
| 3570000 | Ringer B. Braun | Ila |
| 3570010 | Ringer B. Braun | Ila |
| 3570020 | Ringer B. Braun | Ila |
| 3570030 | Ringer B. Braun | Ila |
| 3570040 | Ringer B. Braun | Ila |
| 3570050 | Ringer B. Braun | Ila |
| 3570060 | Ringer B. Braun | Ila |
| 3570200 | Ringer B. Braun | Ila |
| FREU864 | Ringer B. Braun | Ila |
| FREU924 | Ringer B. Braun | Ila |
| FREU944 | Ringer B. Braun | Ila |
| FREU964 | Ringer B. Braun | Ila |
| FREU984 | Ringer B. Braun | Ila |
| 3570490 | Ringer-Lactate B. Braun | Ila |
| 3570500 | Ringer-Lactate B. Braun | Ila |
| 3570510 | Ringer-Lactate B. Braun | Ila |
| 3570520 | Ringer-Lactate B. Braun | Ila |
| 3570530 | Ringer-Lactate B. Braun | Ila |
| FREU920 | Ringer-Lactate B. Braun | Ila |

Dichiarazione di conformità

La sottoscritta

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

con la presente, dichiara sotto la propria responsabilità che i/il prodotto/i

Aqua B. Braun
Aqua Purificata
Sterile Water for Irrigation
Gedestilleerd water
NaCl 0.9% B. Braun
Sodium Chloride 0.9% for Irrigation
Natriumchloride 0,9%
Solución para Irrigación Vitulia NaCl 0,9%
0,9% w/v Sodium Chloride Irrigation Solution
Isotonische Natriumchlorid-Lösung ad us. Vet. B. Braun
Vet Care
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 i numeri articolo vedere l'allegato I)

è/sono in conformità con le seguenti Direttive

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 del Consiglio sopra citata

Classificazione

secondo l'allegato IX della Direttiva del Consiglio sopra nominata
Classe IIa

Organismo Notificato

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



Dichiarazione di conformità

Data del primo marchio CE

06-2003

Valido fino

10-06-2021

Melsungen, 10-06-2016

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Care Division

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