

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

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**

der Produktgruppe Spüllösungen zur topischen,
intra- und postoperativen Verwendung
(Artikelnummern siehe Anlage 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**

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
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.: **20**
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Gültig bis
2024-05-26

Valid until
2024-05-26

Effective

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

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3570170	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
3570460	Estericlean NaCl 0,9%	Ila
3570470	NaCl 0.9% B. Braun	Ila
3570480	NaCl 0.9% B. Braun	Ila
3570900	NaCl 0,9% B. Braun	Ila
3637006	Sodium Chloride 0,9% for Irrigation	Ila
3637010	Sodium Chloride 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
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

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3570060	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

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Title: Declaration of Conformity - TD-004 Initiator: Maria-Roxana M Tranca

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