

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

**Konformitätserklärung**  
**Declaration of Conformity**

Document-No.: **TD-004**  
Revision-No.: **20**  
Effective Date: **Last date of signature**  
Page: **2 of 5**

Effective

<b>Gültig bis</b> 2024-05-26	<b>Valid until</b> 2024-05-26
---------------------------------	----------------------------------

Effective

**Konformitätserklärung**  
**Declaration of Conformity**Document-No.: **TD-004**Revision-No.: **20**Effective Date: **Last date of signature**Page: **3 of 5****Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product Name</b>	<b>Klasse / Class</b>
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

**Konformitätserklärung**  
**Declaration of Conformity**

Document-No.: **TD-004** EffectiveRevision-No.: **20**Effective Date: **Last date of signature**Page: **4 of 5**

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

Konformitätserklärung  
Declaration of Conformity

Document-No.: **TD-004**  
Revision-No.: **20**  
Effective Date: **Last date of signature**  
Page: **5 of 5**

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

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: Monday, 12 June 2023, 08:10 W. Europe Daylight Time  
Meaning: Document signed as Author  
=====

UserName: Ritz, Frank (ritzfrde)  
Title: HC-QM DE08 Head QM CoE Pharmaceuticals  
Date: Monday, 12 June 2023, 08:56 W. Europe Daylight Time  
Meaning: Approve Document  
=====

UserName: Weiss, Gabriele (weisgade)  
Title: Vice President GRA  
Date: Tuesday, 13 June 2023, 09:21 W. Europe Daylight Time  
Meaning: Approve Document  
=====

UserName: Buenger, Joachim (buenjode)  
Title: Director Template & Submission Mgmt  
Date: Saturday, 17 June 2023, 14:07 W. Europe Daylight Time  
Meaning: Approve Document  
=====