

## 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

**Omnican® Never Share**

Spritze, dosierte Verabreichung, steril  
(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie  
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni  
1993 über Medizinprodukte,  
geändert durch Richtlinie 2007/47/EG

**Konformitätsbewertungsverfahren**  
nach Anhang II  
ohne Abschnitt 4  
der oben genannten Richtlinie

**Klassifizierung**  
gemäß Anhang IX der oben genannten  
Richtlinie:  
Klasse IIa

**Benannte Stelle**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Deutschland  
Kennnummer 0123

**Datum der ersten CE-Kennzeichnung**  
2007-04

**Gültig bis**  
2024-05-26

hereby declare in our own responsibility  
that the product/s

**Omnican® Never Share**

Syringes, metered delivery, sterile  
(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14 June 1993  
concerning Medical Devices,  
amended by Directive 2007/47/EG

**Conformity assessment procedure**  
according to annex II  
without part 4  
of the Directive named above

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

**Notified body**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Germany  
Identification number 0123

**Date of first CE-marking**  
2007-04

**Valid until**  
2024-05-26

**Effective**

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product Name</b>	<b>Klasse / Class</b>
9151142S	Omnican® Never Share, white	Ila
9151143S	Omnican® Never Share, blue	Ila
9151144S	Omnican® Never Share, green	Ila
9151145S	Omnican® Never Share, yellow	Ila
9151146S	Omnican® Never Share, pink	Ila

**Effective**

### Amendment Information

Version	Description of the changes
06	Annual revision acc. to TÜV audit 05-2009
07	Annual revision acc. to TÜV audit 05-2009 Version 1: BBMAG OPM; Version 2: BBMAG
08	Adaption to SOP HO-DDDD-M-5-2-05-715
09	Adaption of conformity assessment procedure to "according to annex II without part 4"
10	Adaptation of validity to the validity date of the EC certificate (and to the MDR deadline)

Title: Declaration of Conformity - 020-001(b) - Omnican Never Share Initiator: Anna Heil

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

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