

**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® F,
IBSA FSH/LH**

Einmal-Feindosierungsspritze

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 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**
2003-04**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Omnican® F,
IBSA FSH/LH**

Single use fine dosage syringe

(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**
2003-04**Valid until**
2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product Name	Klasse / Class
9151130S	Omnican® F	Ila
9161502	Omnican® F	Ila
9161502S	Omnican® F	Ila
9161530S	IBSA FSH/LH	Ila

Amendment Information

Version	Description of changes
15.0	Adaption to SOP HO-DDDD-M-5-2-05-715
16.0	Adaption of conformity assessment procedure to "according to annex II without part 4"
17.0	Adaptation of validity to the validity date of the EC certificate (and to the MDR deadline)
18.0	Add art. no. 9161530S
19.0	Change product name of art. no. 9161530S from "IBSA FSH/H" to "IBSA FSH/LH"

Title: Declaration of Conformity - 020-001(c) - Omnican F Initiator: Caroline ? Herbst

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

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