

**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**Omnifix®-F Slip,
Omnifix® Slip,
Omnifix® Lock**

Einmalspritzen, 3-teilig für Regionalanästhesie

(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 (ausgenommen Abschnitt 4)
nach Anhang VII und V
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa
Klasse I steril Messfunktion**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**
1996-03hereby declare in our own responsibility
that the product/s**Omnifix®-F Slip,
Omnifix® Slip,
Omnifix® Lock**Single-use Syringes, 3-piece for Regional
Anaesthesia

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June
1993
concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according to annex II (excluding section 4)
according to annex VII and V
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class IIa
Class I sterile measuring function**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Date of first CE-marking**
1996-03

Gültig bis
2024-05-26

Valid until
2024-05-26

Anlage I / Attachment I

Art.-Nr./Art. no.	Produktname/ Product name	Klasse / Class
4616003	Omnifix® Slip	I steril Messfunktion / I sterile measuring function
4616005	Omnifix® Slip	I steril Messfunktion / I sterile measuring function
4616014	Omnifix® Slip	I steril Messfunktion / I sterile measuring function
4616021	Omnifix® Slip	I steril Messfunktion / I sterile measuring function
4617003	Omnifix® Lock	Ila
4617006	Omnifix® Lock	Ila
4617014	Omnifix® Lock	Ila
4617021	Omnifix® Lock	Ila
4617508F-01	Omnifix® Lock	Ila
9164001	Omnifix®-F Slip	I steril Messfunktion / I sterile measuring function

Amendment Information

Version	Description of the changes
01	Initial version for art. no. 4616003, 4616005, 4616014, 4617003, 4617006, 4617014, 4617021, 9164001
02	Add art. no. 4616021
03	Add art. no. 4617508F-01
04	Update validity

Title: Declaration of Conformity - 094-008 - Omnifix NRfit Initiator: Caroline ? Herbst

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

UserName: Herbst, Caroline (fuehcade)
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Meaning: Document signed as Author
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Meaning: Approve Document
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