

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

**AS Luer Solo 1 ml,
Levovist Luer Lock,
Omnifix® Luer Duo,
Omnifix® Luer Solo,
Omnifix® Luer Lock Duo,
Omnifix® Luer Lock Solo,
Omnifix® Luer Plus/Duo**
Einmalspritzen, 3-teilig

**Omnifix®-F Luer Duo,
Omnifix®-F Luer Solo,
Omnifix®-H Luer Solo**
Feindosierungsspritzen, 3-teilig

(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 (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

hereby declare in our own responsibility
that the product/s

**AS Luer Solo 1 ml,
Levovist Luer Lock,
Omnifix® Luer Duo,
Omnifix® Luer Solo,
Omnifix® Luer Lock Duo,
Omnifix® Luer Lock Solo,
Omnifix® Luer Plus/Duo**
Single-use Syringes, 3-piece
(Hypodermic Syringes)

**Omnifix®-F Luer Duo,
Omnifix®-F Luer Solo,
Omnifix®-H Luer Solo**
Single-use Syringes, 3-piece
(Fine Dosage Syringes)

(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

**Konformitätserklärung
Declaration of Conformity**Document-No.: **094-001**Revision-No.: **07**Effective Date: **Last date of
signature**Page: **2 of 5****Benannte Stelle**

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

Datum der ersten CE-Kennzeichnung

1996-03

Gültig bis

2022-04-03

Notified Body

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

Date of first CE-marking

1996-03

Valid until

2022-04-03

Melsungen, 2017-04-03

B. Braun Melsungen AG

i. V.



Thomas Stefan Brand

**Vice President Quality Management for non-active Medical
Devices**

Melsungen, 2017-04-03

B. Braun Melsungen AG

i. V.



Gudrun Henke

Senior Manager Regulatory Affairs CoE IV-Systems

Konformitätserklärung
Declaration of ConformityDocument-No.: **094-001**Revision-No.: **07**Effective Date: **Last date of
signature**Page: **3 of 5****Anlage I / Attachment I**

Art.-Nr. /	Produktname /	Klasse / Class
Art. No.	Product name	
4610075F	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4610083F	Omnifix® Luer Lock Solo	Ila
4610210F	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4610361	Omnifix® Luer Plus/Duo	Ila
4616022V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616025BR	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616025V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616057BR	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616057V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616103BR	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616103V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616200BR	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616200V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616200V-03	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616308F	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616502F	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616502F-03	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4617022BR	Omnifix® Luer Lock Solo	Ila
4617022V	Omnifix® Luer Lock Solo	Ila
4617022V-03	Omnifix® Luer Lock Solo	Ila
4617024-03	Omnifix® Luer Lock Duo	Ila
4617029V	Omnifix® Luer Lock Solo	Ila
4617030	Omnifix® Luer Lock Solo	Ila
4617053BR	Omnifix® Luer Lock Solo	Ila
4617053V	Omnifix® Luer Lock Solo	Ila
4617053V-03	Omnifix® Luer Lock Solo	Ila
4617100BR	Omnifix® Luer Lock Solo	Ila
4617100CA	Omnifix® Luer Lock Solo	Ila
4617100V	Omnifix® Luer Lock Solo	Ila
4617100V-03	Omnifix® Luer Lock Solo	Ila

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Art.-Nr. /	Produktname /	Klasse / Class
Art. No.	Product name	
4617207BR	Omnifix® Luer Lock Solo	Ila
4617207V	Omnifix® Luer Lock Solo	Ila
4617207V-03	Omnifix® Luer Lock Solo	Ila
4617304F	Omnifix® Luer Lock Solo	Ila
4617304F-03	Omnifix® Luer Lock Solo	Ila
4617509F	Omnifix® Luer Lock Solo	Ila
4617509F-03	Omnifix® Luer Lock Solo	Ila
4617510F-06	Omnifix® Luer Lock Solo	Ila
4641021-03	Omnifix® Luer Lock Duo	Ila
4642922-03	Omnifix® Luer Duo	Ila
4643003F	Omnifix® Luer Duo	Ila
4643004F	Omnifix® Luer Duo	Ila
4643011C	Omnifix® Luer Duo	Ila
4643011V	Omnifix® Luer Duo	Ila
4643040F	Omnifix® Luer Duo	Ila
4643100C	Omnifix® Luer Duo	Ila
4643100V	Omnifix® Luer Duo	Ila
4643102C	Omnifix® Luer Duo	Ila
4643102V	Omnifix® Luer Duo	Ila
4643119C	Omnifix® Luer Duo	Ila
4643119V	Omnifix® Luer Duo	Ila
4643121-03	Omnifix® Luer Duo	Ila
4643123	Omnifix® Luer Duo	Ila
4643123-03	Omnifix® Luer Duo	Ila
4643124-03	Omnifix® Luer Duo	Ila
4643127C	Omnifix® Luer Duo	Ila
4643127V	Omnifix® Luer Duo	Ila
4643135C	Omnifix® Luer Duo	Ila
4643135V	Omnifix® Luer Duo	Ila
4643135V-03	Omnifix® Luer Duo	Ila
4643161	Omnifix® Luer Duo	Ila
4643223-03	Omnifix® Luer Duo	Ila

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Art.-Nr. /	Produktname /	Klasse / Class
Art. No.	Product name	
4643224-03	Omnifix® Luer Duo	Ila
4643523-03	Omnifix® Luer Lock Duo	Ila
4645222-03	Omnifix® Luer Duo	Ila
4645524-03	Omnifix® Luer Lock Duo	Ila
9161406BR	Omnifix®-F Luer Solo	I steril Messfunktion / I sterile measuring function
9161406V	Omnifix®-F Luer Solo	I steril Messfunktion / I sterile measuring function
9161408V	Omnifix®-F Luer Solo	I steril Messfunktion / I sterile measuring function
9161426-03	Omnifix®-F Luer Duo	Ila
9161440	AS Luer Solo 1 ml	I steril Messfunktion / I sterile measuring function
9161465V	Omnifix®-F Luer Duo	Ila
9162607BR	Omnifix®-H Luer Solo	I steril Messfunktion / I sterile measuring function
9162607V	Omnifix®-H Luer Solo	I steril Messfunktion / I sterile measuring function
9162909BR	Omnifix®-H Luer Solo	I steril Messfunktion / I sterile measuring function
9162909V	Omnifix®-H Luer Solo	I steril Messfunktion / I sterile measuring function
9200827	Levovist Luer Lock	Ila
9200835	Levovist Luer Lock	Ila
9202145F	Omnifix®-F Luer Duo	Ila