

**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,
Omnifix® Luer Duo,
Omnifix® Luer Solo,
Omnifix® Luer Lock Duo,
Omnifix® Luer Lock Solo,
Omnifix® Luer Plus/Duo,
SOFT-JECT® Luer Lock Solo,
SOFT-JECT® Luer Solo**
Einmalspritzen, 3-teilig**Omnifix®-F Luer Duo,
Omnifix®-F Luer Lock Solo,
Omnifix®-F Luer Solo,
Omnifix®-H Luer Solo,
SOFT-JECT®-F Luer Solo**
Feindosierungsspritzen, 3-teilig

(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 Richtliniehereby declare in our own responsibility
that the product/s**AS Luer Solo 1 ml,
Omnifix® Luer Duo,
Omnifix® Luer Solo,
Omnifix® Luer Lock Duo,
Omnifix® Luer Lock Solo,
Omnifix® Luer Plus/Duo,
SOFT-JECT® Luer Lock Solo,
SOFT-JECT® Luer Solo**
Single-use Syringes, 3-piece
(Hypodermic Syringes)**Omnifix®-F Luer Duo,
Omnifix®-F Luer Lock Solo,
Omnifix®-F Luer Solo,
Omnifix®-H Luer Solo,
SOFT-JECT®-F 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

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

1996-03

Gültig bis

2024-05-26

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

Valid until

2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
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
4616050V	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
4616107V	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
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
4617029LDS	Omnifix® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
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

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4617100V	Omnifix® Luer Lock Solo	Ila
4617100V-03	Omnifix® Luer Lock Solo	Ila
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
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
4643003F	Omnifix® Luer Duo	Ila
4643004F	Omnifix® Luer Duo	Ila
4643011C	Omnifix® Luer Duo	Ila
4643011V	Omnifix® Luer Duo	Ila
4643100V	Omnifix® Luer Duo	Ila
4643102C	Omnifix® Luer Duo	Ila
4643102V	Omnifix® Luer Duo	Ila
4643105V	Omnifix® Luer Duo	Ila
4643119C	Omnifix® Luer Duo	Ila
4643119V	Omnifix® Luer Duo	Ila
4643123	Omnifix® Luer Duo	Ila
4643127C	Omnifix® Luer Duo	Ila
4643127V	Omnifix® Luer Duo	Ila
4643135C	Omnifix® Luer Duo	Ila
4643135V	Omnifix® Luer Duo	Ila
4643161	Omnifix® Luer Duo	Ila
4643523-03	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

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
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
9167006V	Omnifix®-F Luer Lock Solo	I steril Messfunktion / I sterile measuring function
SJ-4616022	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616022-02	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616025	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616025-02	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616057	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616057-02	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616103	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616103-02	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616200	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616200-02	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616308	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616308-02	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616456	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4616456-02	SOFT-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-4617022	SOFT-JECT® Luer Lock Solo	Ila
SJ-4617022-02	SOFT-JECT® Luer Lock Solo	Ila
SJ-4617029	SOFT-JECT® Luer Lock Solo	Ila
SJ-4617029-02	SOFT-JECT® Luer Lock Solo	Ila
SJ-4617053	SOFT-JECT® Luer Lock Solo	Ila
SJ-4617053-02	SOFT-JECT® Luer Lock Solo	Ila
SJ-4617100	SOFT-JECT® Luer Lock Solo	Ila
SJ-4617100-02	SOFT-JECT® Luer Lock Solo	Ila
SJ-4617207	SOFT-JECT® Luer Lock Solo	Ila
SJ-4617207-02	SOFT-JECT® Luer Lock Solo	Ila
SJ-4617304	SOFT-JECT® Luer Lock Solo	Ila
SJ-4617304-02	SOFT-JECT® Luer Lock Solo	Ila

Art.-Nr. /	Produktname /	Klasse / Class
Art. No.	Product name	
SJ-9161406	SOFT-JECT®-F Luer Solo	I steril Messfunktion / I sterile measuring function
SJ-9161406-02	SOFT-JECT®-F Luer Solo	I steril Messfunktion / I sterile measuring function

Amendment Information

Version	Description of changes
15.0	Delete Out of Market art. no. 4642922-03, 4643121-03, 4643124-03, 4643135V-03, 4643223-03, 4643224-03, 4645222-03, 4645524-03, 4643123-03, 4617053V-03, 4617304F-03
16.0	Add art. no. 4616050V, 4616107V, 4617053V-03
17.0	Delete Out of Market art. no. 9202145F
18.0	Delete Out of Market art. no. 4643100C
19.0	Add art. no. SJ-4616022, SJ-4616022-02, SJ-4616025, SJ-4616025-02, SJ-4616057, SJ-4616057-02, SJ-4616103, SJ-4616103-02, SJ-4616200, SJ-4616200-02, SJ-4616308, SJ-4616308-02, SJ-4616456, SJ-4616456-02, SJ-4617022, SJ-4617022-02, SJ-4617029, SJ-4617029-02, SJ-4617053, SJ-4617053-02, SJ-4617100, SJ-4617100-02, SJ-4617207, SJ-4617207-02, SJ-4617304, SJ-4617304-02, SJ-9161406, SJ-9161406-02 previously covered by 094-300

Title: Declaration of Conformity - 094-001 - Omnifix 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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Effective