

**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  
14<sup>th</sup> 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**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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

<b>Art.-Nr. /</b>	<b>Produktname /</b>	<b>Klasse / Class</b>
<b>Art. No.</b>	<b>Product name</b>	
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**

<b>Version</b>	<b>Description of changes</b>
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:

UserName: Herbst, Caroline (fuehcade)  
Title: Administrator Regulatory Affairs  
Date: Friday, 21 May 2021, 15:44 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Seidel, Stefan (seidstde)  
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems  
Date: Friday, 21 May 2021, 16:47 W. Europe Daylight Time  
Meaning: Approve Document

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UserName: Brand, Thomas (brantode)  
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices  
Date: Monday, 24 May 2021, 19:36 W. Europe Daylight Time  
Meaning: Approve Document

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**Effective**