

**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 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

**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**

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**Anlage I / Attachment I**

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