

**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**Amefa Luer Solo,  
AS Plus Luer Solo 1 ml,  
Injekt® Luer Duo,  
Injekt® Luer Lock Solo,  
Injekt® Luer Solo,  
PP 5,3 ml Luer Solo**  
Einmalspritzen, 2-teilig**Injekt®-F Luer Duo,  
Injekt®-F Luer Solo,  
Injekt®-H Luer Duo,  
Injekt®-H Luer Solo**  
Feindosierungsspritzen, 2-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 Richtlinie  
**Klassifizierung**  
gemäß Anhang IX der  
oben genannten Richtlinie  
Klasse IIa  
Klasse I steril Messfunktionhereby declare in our own responsibility  
that the product/s**Amefa Luer Solo,  
AS Plus Luer Solo 1 ml,  
Injekt® Luer Duo,  
Injekt® Luer Lock Solo,  
Injekt® Luer Solo,  
PP 5,3 ml Luer Solo**  
Single-use Syringes, 2-piece  
(Hypodermic Syringes)**Injekt®-F Luer Duo,  
Injekt®-F Luer Solo,  
Injekt®-H Luer Duo,  
Injekt®-H Luer Solo**  
Single-use Syringes, 2-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

**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

**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>
4602200	Amefa Luer Solo	I steril Messfunktion / I sterile measuring function
4602218	Amefa Luer Solo	I steril Messfunktion / I sterile measuring function
4602226	Amefa Luer Solo	I steril Messfunktion / I sterile measuring function
4602234	Amefa Luer Solo	I steril Messfunktion / I sterile measuring function
4606027V	Injekt® Luer Solo	I steril Messfunktion / I sterile measuring function
4606027V-03	Injekt® Luer Solo	I steril Messfunktion / I sterile measuring function
4606051V	Injekt® Luer Solo	I steril Messfunktion / I sterile measuring function
4606051V-03	Injekt® Luer Solo	I steril Messfunktion / I sterile measuring function
4606058	PP 5,3 ml Luer Solo	I steril Messfunktion / I sterile measuring function
4606108V	Injekt® Luer Solo	I steril Messfunktion / I sterile measuring function
4606108V-03	Injekt® Luer Solo	I steril Messfunktion / I sterile measuring function
4606205V	Injekt® Luer Solo	I steril Messfunktion / I sterile measuring function
4606205V-03	Injekt® Luer Solo	I steril Messfunktion / I sterile measuring function
4606701V	Injekt® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
4606710V	Injekt® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
4606728V	Injekt® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
4606736V	Injekt® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
4645021-03	Injekt® Luer Duo	Ila
4645022C	Injekt® Luer Duo	Ila
4645022V	Injekt® Luer Duo	Ila
4645023-03	Injekt® Luer Duo	Ila
4645024-03	Injekt® Luer Duo	Ila
4645049	Injekt® Luer Duo	Ila
4645057C	Injekt® Luer Duo	Ila
4645057V	Injekt® Luer Duo	Ila
4645065C	Injekt® Luer Duo	Ila
4645070	Injekt® Luer Duo	Ila
4645103C	Injekt® Luer Duo	Ila
4645103V	Injekt® Luer Duo	Ila
4645122-03	Injekt® Luer Duo	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4645200C	Injekt® Luer Duo	Ila
4645200V	Injekt® Luer Duo	Ila
4645200V-03	Injekt® Luer Duo	Ila
4647068	Injekt® Luer Duo	Ila
4647220	Injekt® Luer Duo	Ila
4647240-03	Injekt® Luer Duo	Ila
9161450	AS Plus Luer Solo 1 ml	I steril Messfunktion / I sterile measuring function
9166017V	Injekt®-F Luer Solo	I steril Messfunktion / I sterile measuring function
9166033V	Injekt®-F Luer Duo	Ila
9166106V	Injekt®-H Luer Solo	I steril Messfunktion / I sterile measuring function
9166203V	Injekt®-H Luer Solo	I steril Messfunktion / I sterile measuring function
9166254V	Injekt®-H Luer Solo	I steril Messfunktion / I sterile measuring function
9166297	Injekt®-H Luer Duo	Ila

**Amendment Information**

<b>Version</b>	<b>Description of changes</b>
4.0	Delete Out of Market art. no. 9166441
5.0	Delete Out of Market art. no. 4645002, 4645005
6.0	Update validity
7.0	Delete Out of Market art. no. 4647220-03, 4647222-03
8.0	Delete Out of Market art. no. 4645030

Title: Declaration of Conformity - 094-002 - Injekt 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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