

**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/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**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 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**

Effective

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

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
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
4645030	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

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4645122-03	Injekt® Luer Duo	Ila
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

Version	Description of the changes
3.0	Delete Out of Market art. no. 4645065
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

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:

UserName: Herbst, Caroline (fuehcade)
Title: Administrator Regulatory Affairs
Date: Monday, 12 October 2020, 09:09 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Monday, 12 October 2020, 16:43 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Friday, 16 October 2020, 23:48 W. Europe Daylight Time
Meaning: Approve Document
=====