

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,
NORM-JECT® Luer Lock Solo,
NORM-JECT® Luer Solo**
Einmalspritzen, 2-teilig

**Injekt®-F Luer Duo,
Injekt®-F Luer Solo,
Injekt®-H Luer Duo,
Injekt®-H Luer Solo,
NORM-JECT®-F 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

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,
NORM-JECT® Luer Lock Solo,
NORM-JECT® 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,
NORM-JECT®-F 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

Effective

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
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
4645022UA	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
4645057UA	Injekt® Luer Duo	Ila
4645065C	Injekt® Luer Duo	Ila
4645070	Injekt® Luer Duo	Ila
4645103C	Injekt® Luer Duo	Ila

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Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4645103V	Injekt® Luer Duo	Ila
4645103UA	Injekt® Luer Duo	Ila
4645122-03	Injekt® Luer Duo	Ila
4645200C	Injekt® Luer Duo	Ila
4645200V	Injekt® Luer Duo	Ila
4645200V-03	Injekt® Luer Duo	Ila
4645200UA	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
NJ-4606027	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606027-02	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606051	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606051-02	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606067	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606067-02	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606108	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606108-02	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606110	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606110-02	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606205	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606205-02	NORM-JECT® Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-4606701	NORM-JECT® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
NJ-4606701-02	NORM-JECT® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
NJ-4606710	NORM-JECT® Luer Lock Solo	I steril Messfunktion / I sterile measuring function

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
NJ-4606710-02	NORM-JECT® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
NJ-4606728	NORM-JECT® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
NJ-4606728-02	NORM-JECT® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
NJ-4606736	NORM-JECT® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
NJ-4606736-02	NORM-JECT® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
NJ-4606755BMS	NORM-JECT® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
NJ-9166017	NORM-JECT®-F Luer Solo	I steril Messfunktion / I sterile measuring function
NJ-9166017-02	NORM-JECT®-F Luer Solo	I steril Messfunktion / I sterile measuring function

Amendment Information

Version	Description of changes
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
9.0	Add art. no. NJ-4606755BMS
10.0	Add art. no. NJ-4606027, NJ-4606027-02, NJ-4606051, NJ-4606051-02, NJ-4606067, NJ-4606067-02, NJ-4606108, NJ-4606108-02, NJ-4606110, NJ-4606110-02, NJ-4606205, NJ-4606205-02, NJ-4606701, NJ-4606701-02, NJ-4606710, NJ-4606710-02, NJ-4606728, NJ-4606728-02, NJ-4606736, NJ-4606736-02, NJ-9166017, NJ-9166017-02 previously covered by 092-300
11.0	Add art. no. 4645022UA, 4645057UA, 4645103UA, 4645200UA

Effective

Title: Declaration of Conformity - 094-002 - Injekt Initiator: Katharina Birkelbach

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Birkelbach, Katharina (birkkade)
Title: HC-RA-DE08E - Junior Manager Regulatory Affairs
Date: Wednesday, 23 November 2022, 17:09 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Wednesday, 23 November 2022, 17:50 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Thursday, 24 November 2022, 17:21 W. Europe Daylight Time
Meaning: Approve Document
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