

Konformitätserklärung Declaration of Conformity

Wir

We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201

erklären in eigener Verantwortung,
dass die Produkte

Injekt® Luer Solo
PP 5,3 ml Luer Solo
AS Plus Luer Solo 1 ml
Injekt®-F Luer Solo
NORM-JECT® Luer Solo
NORM-JECT®-F Luer Solo

2-piece Single-use Syringe with Luer connector
without needle Type Solo

Injekt®-H Luer Solo

2-piece Single-use Syringe with Luer connector
without needle with Heparin Scale Type Solo

Injekt® Luer Lock Solo
NORM-JECT® Luer Lock Solo

2-piece Single-use Syringe with Luer lock
connector without needle Type Solo

Injekt® 40 Solo

2-piece Single-use Syringe with Luer connector
without needle with Insulin scale Type Solo

(Artikelnummern und Basic UDI-DI siehe Anlage I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 übereinstimmen

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

hereby declare in our sole responsibility
that the products

Injekt® Luer Solo
PP 5,3 ml Luer Solo
AS Plus Luer Solo 1 ml
Injekt®-F Luer Solo
NORM-JECT® Luer Solo
NORM-JECT®-F Luer Solo

2-piece Single-use Syringe with Luer connector
without needle Type Solo

Injekt®-H Luer Solo

2-piece Single-use Syringe with Luer connector
without needle with Heparin Scale Type Solo

Injekt® Luer Lock Solo
NORM-JECT® Luer Lock Solo

2-piece Single-use Syringe with Luer lock
connector without needle Type Solo

Injekt® 40 Solo

2-piece Single-use Syringe with Luer connector
without needle with Insulin scale Type Solo

(article numbers and Basic UDI-DI see attachment I)

are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745

Conformity Assessment Procedure
according to annex IX
of the Regulation named above

Klassifizierung

gemäß Anhang VIII der oben genannten
Verordnung
Klasse I steril Messfunktion

Benannte Stelle

TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis

gemäß gültigem EU Zertifikat
(Nr. G11 012974 0626)

Classification

according to annex VIII of the Regulation named
above
Class I sterile measuring function

Notified Body

TÜV SÜD Product Service GmbH
Identification number 0123

Valid until

according to our valid EU Certificate
(No. G11 012974 0626)

Anlage I / Attachment I**Basic UDI-DI: 4039239000007732V**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
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
4606108N	Injekt® 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
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
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-4606067-02	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-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-9166017-02	NORM-JECT®-F Luer Solo	I steril Messfunktion / I sterile measuring function

Basic UDI-DI: 4039239000002592A

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

Basic UDI-DI: 403923900000260ZQ

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
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
NJ-4606701-02	NORM-JECT® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
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-4606736-02	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

Basic UDI-DI: 4039239000001220ZK

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
9166408V	Injekt® 40 Solo	I steril Messfunktion / I sterile measuring function

Document amendment information

Version	Description of the changes
1.0	First issue under Medical Device Regulation (MDR)
2.0	Addition of article no. 4606027V, 4606027V-03, 4606051V, 4606051V-03, 4606058, 4606108V, 4606108V-03, 4606205V, 4606205V-03, 4606701V, 4606710V, 4606728V, 4606736V, 9161450, 9166017V, 9166106V, 9166203V, 9166254V, 9166408V, NJ-4606027, NJ-4606027-02, NJ-4606051, NJ-4606051-02, NJ-4606067-02, NJ-4606108, NJ-4606108-02, NJ-4606110, NJ-4606205, NJ-4606205-02, NJ-9166017-02, NJ-4606701-02, NJ-4606710-02, NJ-4606728, NJ-4606728-02, NJ-4606736-02, and NJ-4606755BMS based on MDR conversion project S.101-0468.01 (change control HC-CHC-M-DIV-2024).

Title: Declaration of Conformity - 092-001 - MDR - 2-piece syringes (Injekt, others) Initiator: Jascha T Manschwetus

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

UserName: Manschwetus, Jascha (mansjsde)
Title: Junior Manager Regulatory Affairs | CoE Infusion & Pain Therapy
Date: Monday, 08 April 2024, 15:33 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Tuesday, 09 April 2024, 09:47 W. Europe Daylight Time
Meaning: Approve Document

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Tuesday, 09 April 2024, 15:42 W. Europe Daylight Time
Meaning: Approve Document
