

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
Basis UDI-DI: 4039239000007732V
(Artikelnummern siehe Anlage I)

Injekt®-H Luer Solo
2-piece Single-use Syringe with Luer connector
without needle with Heparin Scale Type Solo
Basis UDI-DI: 4039239000002592A
(Artikelnummern siehe Anlage I)

Injekt® Luer Lock Solo
NORM-JECT® Luer Lock Solo
2-piece Single-use Syringe with Luer lock
connector without needle Type Solo
Basis UDI-DI: 403923900000260ZQ
(Artikelnummer siehe Anlage I)

Injekt® 40 Solo
2-piece Single-use Syringe with Luer connector
without needle with Insulin scale Type Solo
Basis UDI-DI: 4039239000001220ZK
(Artikelnummer siehe Anlage I)

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
Basic UDI-DI: 4039239000007732V
(article numbers see attachment I)

Injekt®-H Luer Solo
2-piece Single-use Syringe with Luer connector
without needle with Heparin Scale Type Solo
Basic UDI-DI: 4039239000002592A
(article numbers see attachment I)

Injekt® Luer Lock Solo
NORM-JECT® Luer Lock Solo
2-piece Single-use Syringe with Luer lock
connector without needle Type Solo
Basic UDI-DI: 403923900000260ZQ
(article numbers see attachment I)

Injekt® 40 Solo
2-piece Single-use Syringe with Luer connector
without needle with Insulin scale Type Solo
Basic UDI-DI: 4039239000001220ZK
(article numbers see attachment I)

**Injekt® Luer Duo
Injekt®-F Luer Duo**

2-piece Single-use Syringe with Luer connector
with needle Type Duo
Basis UDI-DI: 40392390000007752Z
(Artikelnummern siehe Anlage I)

Injekt®-H Luer Duo

2-piece Single-use Syringe with Luer connector
with needle with Heparin scale Type Duo
Basis UDI-DI: 40392390000007742X
(Artikelnummern siehe Anlage I)

Injekt® 40 Duo

2-piece Single-use Syringe with Luer connector
with needle with Insulin scale Type Duo
Basis UDI-DI: 403923900000121823
(Artikelnummern siehe Anlage I)

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

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Klassifizierung

gemäß Anhang VIII der oben genannten
Verordnung
Klasse I steril Messfunktion
oder
Klasse IIa

Benannte Stelle

TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis

gemäß gültiger EU Zertifikate
Nr. G11 012974 0626 (Klasse I steril
Messfunktion)
oder
Nr. G10 012974 0611 (Klasse IIa)

**Injekt® Luer Duo
Injekt®-F Luer Duo**

2-piece Single-use Syringe with Luer connector
with needle Type Duo
Basic UDI-DI: 40392390000007752Z
(article numbers see attachment I)

Injekt®-H Luer Duo

2-piece Single-use Syringe with Luer connector
with needle with Heparin scale Type Duo
Basic UDI-DI: 40392390000007742X
(article numbers see attachment I)

Injekt® 40 Duo

2-piece Single-use Syringe with Luer connector
with needle with Insulin scale Type Duo
Basic UDI-DI: 403923900000121823
(article numbers 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

Classification

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

Notified Body

TÜV SÜD Product Service GmbH
Identification number 0123

Valid until

according to our valid EU Certificates
No. G11 012974 0626 (class I sterile measuring
function)
or
No. G10 012974 0611 (class IIa)

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

Basic UDI-DI: 40392390000007752Z

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4645022C	Injekt® Luer Duo	Ila
4645022UA	Injekt® Luer Duo	Ila
4645022V	Injekt® Luer Duo	Ila
4645057C	Injekt® Luer Duo	Ila
4645057UA	Injekt® Luer Duo	Ila
4645057V	Injekt® Luer Duo	Ila
4645065C	Injekt® Luer Duo	Ila
4645103C	Injekt® Luer Duo	Ila
4645103UA	Injekt® Luer Duo	Ila
4645103V	Injekt® Luer Duo	Ila
4645200C	Injekt® Luer Duo	Ila
4645200UA	Injekt® Luer Duo	Ila
4645200V	Injekt® Luer Duo	Ila
4647220	Injekt® Luer Duo	Ila
9166033V	Injekt®-F Luer Duo	Ila

Basic UDI-DI: 40392390000007742X

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
9166297	Injekt®-H Luer Duo	Ila

Basic UDI-DI: 403923900000121823

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
9166432C	Injekt® 40 Duo	Ila
9166432V	Injekt® 40 Duo	Ila

Document amendment information

Version	Description of the changes
1.0	First issue under Medical Device Regulation (MDR)
2.0	Addition of article nos. 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).
3.0	Addition of article nos. 4645022C, 4645022UA, 4645022V, 4645057C, 4645057UA, 4645057V, 4645065C, 4645103C, 4645103UA, 4645103V, 4645200C, 4645200UA, 4645200V, 4647220, 9166033V, 9166297, 9166432C, 9166432V based on MDR conversion project S.101-0468.01 (change control HC-CHC-M-DIV-2024).
4.0	Correction of article number 9166106V to 9166297 under Basic-UDI-DI 40392390000007742X in Attachement I.

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: Friday, 24 May 2024, 17:14 W. Europe Daylight Time
Meaning: Document signed as Author

=====

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Friday, 24 May 2024, 17:34 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, 24 May 2024, 17:48 W. Europe Daylight Time
Meaning: Approve Document

=====