

## 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**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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**

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

**Basic UDI-DI: 40392390000007752Z**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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**

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

**Basic UDI-DI: 403923900000121823**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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:

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