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

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
Basis UDI-DI: 40392390000007732V
(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: 40392390000002592A
(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: 4039239000000260ZQ
(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)

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: 40392390000007732V
(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: 40392390000002592A
(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: 4039239000000260ZQ
(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)

Effective

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)

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Anlage I / Attachment I

Basic UDI-DI: 40392390000007732V

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: 40392390000002592A

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: 40392390000000260ZQ

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

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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: 403923900000007752Z

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

Basic UDI-DI: 4039239000000742X

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

Basic UDI-DI: 403923900000121823

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

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
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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
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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
==========

Effective

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 012974 0626 Rev. 10

Manufacturer:

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

SRN Manufacturer - DE-MF-000000201

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11 012974 0626 Rev. 10

Report No.: 713311455

Preceding Certificate No.: G11 012974 0626 Rev. 09

Valid from: 2024-10-07
Valid until: 2026-12-14

Date of Initial Issuance: 2021-12-15

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-10-07

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 012974 0626 Rev. 10

Classification:	Class I
Device Group:	A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A060304 - INTRA-OPERATION FLUID COLLECTION DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M040102 - FIXING DRESSINGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A020101 - LOSS-OF-RESISTANCE SYRINGES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A070501 - CAPS OR OBTURATORS, NON-PERFORABLE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A020299 - REUSABLE SYRINGES - OTHER
Device Properties:	MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A020108 - ENTERAL FEEDING SYRINGES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A0704 - SYSTEMS FOR RECONSTITUTION AND ADMINISTRATION OF PHARMACEUTICALS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.2 - Sterilisation by irradiation

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EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 012974 0626 Rev. 10

Classification:	Class I
Device Group:	A030101 - INFUSION CONTROLLERS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.2 - Sterilisation by irradiation MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A010104 - NEEDLES FOR VIAL COLLECTION
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A040101 - ADMINISTRATION AND ASPIRATION FILTERS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A020106 - INSULIN SYRINGES, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A019001 - BLUNT NEEDLES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A030103 - ENTERAL FEEDING CONTROLLERS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A0199 - NEEDLES - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A060301 - COLLECTION BAGS AND OTHER CONTAINERS FOR DRAINAGES AND FISTULAS, SINGLE USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 012974 0626 Rev. 10

Classification:	Class I
Device Group:	A060303 - URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2021-12-15	713207236	-
01	2022-10-25	713230661	-
02	2023-03-29	713279829	Supplemented: Device(s)/group of device(s) added
03	2023-06-06	713282404	Supplemented: Device(s)/group of device(s) added
04	2023-06-08	713300468 / 713300479	Supplemented: Device(s)/group of device(s) added
05	2023-09-22	713270138	Supplemented: Device(s)/group of device(s) added
06	2023-10-27	713307156	Supplemented: Device(s)/group of device(s) added
07	2024-02-14	713315087 / 713316915 / 713316918 / 713316911 / 713316917 / 713316913	Supplemented: Device(s)/group of device(s) added
08	2024-04-19	713330451 / 713330449 / 713317014	Supplemented: Device(s)/group of device(s) added
09	2024-09-05	713339659	Supplemented: Device(s)/group of device(s) added
10	2024-10-07	713311455	Supplemented: Device(s)/group of device(s) added

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