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

Omnifix® Luer Solo
Omnifix®-F Luer Solo
3-piece Single-use Syringe with Luer connector without needle Type Solo
Basis UDI-DI: 4039239000000261ZS
(Artikelnummern siehe Anlage I)

Omnifix®-H Luer Solo
3-piece Single-use Syringe with Luer connector with Heparin scale without needle Type Solo
Basis UDI-DI: 4039239000000263ZW
(Artikelnummern siehe Anlage I)

Omnifix® Luer Lock Solo
Omnifix®-F Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo
Basis UDI-DI: 4039239000000262ZU
(Artikelnummern siehe Anlage I)

Omnifix® Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo UV-Protect
Basic UDI-DI: 403923900000207022
(Artikelnummern siehe Anlage I)

Omnifix® 40 Solo
Omnifix® 100 Solo
3-piece Single-use Syringe with Luer connector without needle with Insulin scale Type Solo
Basis UDI-DI: 403923900000121925
(Artikelnummern siehe Anlage I)

hereby declare in our own responsibility that the products

Omnifix® Luer Solo
Omnifix®-F Luer Solo
3-piece Single-use Syringe with Luer connector without needle Type Solo
Basic UDI-DI: 4039239000000261ZS
(article numbers see attachment I)

Omnifix®-H Luer Solo
3-piece Single-use Syringe with Luer connector with Heparin scale without needle Type Solo
Basic UDI-DI: 4039239000000263ZW
(article numbers see attachment I)

Omnifix® Luer Lock Solo
Omnifix®-F Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo
Basic UDI-DI: 4039239000000262ZU
(article numbers see attachment I)

Omnifix® Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo UV-Protect
Basic UDI-DI: 403923900000207022
(article numbers see attachment I)

Omnifix® 40 Solo
Omnifix® 100 Solo
3-piece Single-use Syringe with Luer connector without needle with Insulin scale Type Solo
Basic UDI-DI: 403923900000121925
(article numbers see attachment I)

Effective

Omnifix® Luer Duo
Omnifix®-F Luer Duo
3-piece Single-use Syringe with Luer connector with needle Type Duo
Basis UDI-DI: 403923900000077633
(Artikelnummern siehe Anlage I)

Omnifix® Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo
Basis UDI-DI: 403923900000077735
(Artikelnummern siehe Anlage I)

Omnifix® 40 Duo
Omnifix® 100 Duo
3-piece Single-use Syringe with Luer connector with needle with Insulin scale Type Duo
Basis UDI-DI: 4039239000001217ZW
(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)

Omnifix® Luer Duo
Omnifix®-F Luer Duo
3-piece Single-use Syringe with Luer connector with needle Type Duo
Basic UDI-DI: 403923900000077633
(article numbers see attachment I)

Omnifix® Luer Lock Solo
3-piece Single-use Syringe with Luer Lock connector without needle Type Solo
Basic UDI-DI: 403923900000077735
(article numbers see attachment I)

Omnifix® 40 Duo
Omnifix® 100 Duo
3-piece Single-use Syringe with Luer connector with needle with Insulin scale Type Duo
Basic UDI-DI: 4039239000001217ZW
(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)

Effective

Anlage I / Attachment I

Basic UDI-DI 4039239000000261ZS

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4616022V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616025V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616050V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616057V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616103V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616107V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616200V	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616200V-03	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
4616308F	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
9161406V	Omnifix®-F Luer Solo	I steril Messfunktion / I sterile measuring function
4616502F	Omnifix® Luer Solo	I steril Messfunktion / I sterile measuring function
9167112V	Omnifix®-F Luer Solo	I steril Messfunktion / I sterile measuring function

Basic UDI-DI 4039239000000263ZW

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
9162607V	Omnifix®-H Luer Solo	I steril Messfunktion / I sterile measuring function
9162909V	Omnifix®-H Luer Solo	I steril Messfunktion / I sterile measuring function

Basic UDI-DI 4039239000000262ZU

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4617029LDS	Omnifix® Luer Lock Solo	I steril Messfunktion / I sterile measuring function
9167006V	Omnifix®-F Luer Lock Solo	I steril Messfunktion / I sterile measuring function

Basic UDI-DI 403923900000121925

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
9161309V	Omnifix® 40 Solo	I steril Messfunktion / I sterile measuring function
9161708V	Omnifix® 100 Solo	I steril Messfunktion / I sterile measuring function

Effective

Basic UDI-DI 403923900000077633

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4643011C	Omnifix® Luer Duo	IIa
4643100V	Omnifix® Luer Duo	IIa
4643102C	Omnifix® Luer Duo	IIa
4643102V	Omnifix® Luer Duo	IIa
4643105V	Omnifix® Luer Duo	IIa
4643119C	Omnifix® Luer Duo	IIa
4643119V	Omnifix® Luer Duo	IIa
4643127C	Omnifix® Luer Duo	IIa
4643127V	Omnifix® Luer Duo	IIa
4643135C	Omnifix® Luer Duo	IIa
4643135V	Omnifix® Luer Duo	IIa
4643161	Omnifix® Luer Duo	IIa
9161465V	Omnifix®-F Luer Duo	IIa

Basic UDI-DI 403923900000077735

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4617022V	Omnifix® Luer Lock Solo	IIa
4617022V-03	Omnifix® Luer Lock Solo	IIa
4617029V	Omnifix® Luer Lock Solo	IIa
4617053V	Omnifix® Luer Lock Solo	IIa
4617053V-03	Omnifix® Luer Lock Solo	IIa
4617100CA	Omnifix® Luer Lock Solo	IIa
4617100V	Omnifix® Luer Lock Solo	IIa
4617100V-03	Omnifix® Luer Lock Solo	IIa
4617207V	Omnifix® Luer Lock Solo	IIa
4617207V-03	Omnifix® Luer Lock Solo	IIa
4617304F	Omnifix® Luer Lock Solo	IIa
4617509F	Omnifix® Luer Lock Solo	IIa
4617509F-03	Omnifix® Luer Lock Solo	IIa

Basic UDI-DI 403923900000207022

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4617510F-06	Omnifix® Luer Lock Solo	IIa

Effective

Basic UDI-DI 4039239000001217ZW

Art.-Nr. / Art. No.	**Produktname / Product name**	**Klasse / Class**
9161333V	Omnifix® 40 Duo	IIa
9161376C	Omnifix® 100 Duo	IIa
9161376V	Omnifix® 100 Duo	IIa

Document amendment information

Version	Description of the changes
1.0	Initial Version under Medical Device Regulation (EU) 2017/745.
2.0	Addition of article codes 4616502F, 4617509F and 4617509F-03 Addition of BUDI 403923900000207022 with article code 4617510F-06
3.0	Addition of article code 9167112V

Title: Declaration of Conformity - 094-001 - MDR - Omnifix Initiator: Julia ? Mueller

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

UserName: Mueller, Julia (hampjude)
Title: Senior Manager Regulatory Affairs CoE Infusion & Pain Therapy
Date: Monday, 02 December 2024, 09:20 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: Sunday, 08 December 2024, 13:15 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Seidel, Stefan (seidstde)
Title: Vice President Regulatory Affairs CoE Infusion & Pain Therapy
Date: Monday, 09 December 2024, 10:06 W. Europe Daylight Time
Meaning: Approve Document
==========

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

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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 IIa and Class IIb Devices)

No. G10 012974 0611 Rev. 14

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.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 012974 0611 Rev. 14

Report No.:	713390441
Preceding Certificate No.:	G10 012974 0611 Rev. 13
Valid from:	2026-02-12
Valid until:	2030-03-12
Date of Initial Issuance:	2020-03-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-02-12

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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 IIa and Class IIb Devices)

No. G10 012974 0611 Rev. 14

Classification:	Class IIa
Device Group:	A030101 - INFUSION CONTROLLERS
Intended Purpose:	-

Classification:	Class IIb
Device Group:	Z120303 - INFUSION INSTRUMENTS
Intended Purpose:	Transportable infusion pump that is used in combination with authorized disposables and accessories. The pump is intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and enteral fluids through clinically accepted routes of administration. These routes include, but are not limited to intravenous, intra-arterial, subcutaneous, epidural, irrigation and enteral.

Classification:	Class IIa
Device Group:	A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
Intended Purpose:	-

Classification:	Class IIb
Device Group:	Z12030382 - INFUSION INSTRUMENTS - SOFTWARE ACCESSORIES
Intended Purpose:	Software application platform that is intended to provide bidirectional data communication with authorized medical devices and their accessories. The software application platform is intended to provide gateway functions , visualization of data and configuration of data sets for authorized medical devices and accessories. These data sets include, but are not limited to drug data sets (Drug Library Data) and pump modification data sets (Pump Configuration Data).

Classification:	Class IIa
Device Group:	A010101 - HYPODERMIC NEEDLES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C010101 - PERIPHERAL I.V. CATHETERS
Intended Purpose:	-

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Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 012974 0611 Rev. 14

Classification:	Class IIa
Device Group:	A070199 - ADAPTERS AND CONNECTORS - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A040101 - ADMINISTRATION AND ASPIRATION FILTERS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A070501 - CAPS OR OBTURATORS, NON-PERFORABLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A070502 - CAPS OR OBTURATORS, PERFORABLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A060101 - VACUUM AND GRAVITY DRAINAGE SYSTEMS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A018003 - NEEDLE INTRODUCERS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A010302 - PLEXUS BLOCK NEEDLES AND KITS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0703 - STOPCOCKS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A030103 - ENTERAL FEEDING CONTROLLERS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A030201 - EXTENSIONS
Intended Purpose:	-

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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 IIa and Class IIb Devices)

No. G10 012974 0611 Rev. 14

Classification:	Class IIa
Device Group:	G020201 - NASOGASTRIC INTESTINAL TUBES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A070103 - INFUSION LINES ADAPTERS AND CONNECTORS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A020106 - INSULIN SYRINGES, SINGLE-USE
Intended Purpose:	-

Classification:	Class IIb
Device Group:	A050101 - ELASTOMERIC SYSTEMS - FIXED FLOW
Intended Purpose:	Disposable elastomeric infusion pump system is a non-electrically driven portable infusion device, enabling patients to be treated in an ambulatory manner. The device is indicated for delivering a pre-determined amount of medication to the patient via intravenous, subcutaneous or epidural routes (according to pump model and SPCs of drugs) in a continuous and accurate manner.

Classification:	Class IIa
Device Group:	A060201 - EXTERNAL DRAINAGE CATHETERS AND KITS (ABSCESSES, GALLSTONES, CYSTS)
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0799 - ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A060203 - PLEURAL DRAINAGES WITH VALVE AND KITS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C010280 - CENTRAL VENOUS CATHETERS - ACCESSORIES
Intended Purpose:	-

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No. G10 012974 0611 Rev. 14

Classification:	Class IIa
Device Group:	Z120303 - INFUSION INSTRUMENTS
Intended Purpose:	-

Classification:	Class IIb
Device Group:	V0999 - FLUIDS/GASES FOR CLINICAL/THERAPEUTICAL USE - OTHER
Intended Purpose:	Ready for use, sterile, single use medical device, intended to be used for irrigation applications (irrigation solution)

Classification:	Class IIb
Device Group:	U040102 - KITS WITH DRAINAGE CATHETERS AND INTRODUCERS
Intended Purpose:	Suprapubic catheterization of the bladder after surgery, in case of bladder dysfunction, urinary retention, for diagnostic purposes and for urine assessment

Classification:	Class IIa
Device Group:	U040102 - KITS WITH DRAINAGE CATHETERS AND INTRODUCERS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A020108 - ENTERAL FEEDING SYRINGES
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following: -

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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 IIa and Class IIb Devices)

No. G10 012974 0611 Rev. 14

Revision History:

Rev.	Dated	Report	Description
00	2020-03-13	713169695	-
01	2020-11-19	713169695	-
02	2021-12-28	713188740_CN / 713188421_CN	-
03	2022-11-10	713225005	-
04	2023-03-31	713270133	Supplemented: Device(s)/group of device(s) added
05	2023-05-22	713282403	-
			Supplemented: Device(s)/group of device(s) added
06	2023-11-10	713309567 / 713309565	Supplemented: Device(s)/group of device(s) added
07	2024-02-15	713279371 / 713313043 / 713316921 / 713316928 / 713316930 / 713316916 / 713316919 / 713316912	Supplemented: Device(s)/group of device(s) added
08	2024-04-23	713332639	Supplemented: Device(s)/group of device(s) added
09	2024-05-28	713308882	Supplemented: Device(s)/group of device(s) added
10	2024-09-16	713339665, 713339669, 713339656, 713282405	Supplemented: Device(s)/group of device(s) added
11	2024-11-13	713281980	Supplemented: Device(s)/group of device(s) added
12	2025-03-13	713340251 / 713350098	Renewal of certificate
			Supplemented: Device(s)/group of device(s) added
13	2025-06-03	713375453	Supplemented: Device(s)/group of device(s) added
14	2026-02-12	713390441	Supplemented: Device(s)/group of device(s) added