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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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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(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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EU Quality Management System Certificate (MDR)

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(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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TÜV®

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 das Produkt

hereby declare in our own responsibility that the products

Omnifix®
Spülspritzen steril
Basis UDI-DI: 403923900000029126
(Artikelnummern siehe Anlage I)

Omnifix®
Irrigation syringes sterile
Basic UDI-DI: 403923900000029126
(article numbers see attachment I)

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

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

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

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

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse I steril Messfunktion

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

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Gültig bis
gemäß gültigem EU Zertifikat
(No. G11 012974 0626)

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

Anlage I / Attachment I

Basic UDI-DI: 403923900000029126

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4613503F	Omnifix®	I steril Messfunktion / I sterile measuring function

Effective

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR

Title: Declaration of Conformity - 094-003-MDR - Irrigation Syringes Initiator: Julia2 ? Mueller

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

UserName: Mueller, Julia2 (hampjude)
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Date: Thursday, 23 May 2024, 08:36 W. Europe Daylight Time
Meaning: Document signed as Author
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Date: Thursday, 23 May 2024, 10:18 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Thursday, 23 May 2024, 10:49 W. Europe Daylight Time
Meaning: Approve Document
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Effective