



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](http://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



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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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|---------------------------|--|
| 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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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