



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. 08

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:G11_012974_0626_Rev.08

Report No.: 713330451 / 713330449 / 713317014

Preceding Certificate No.: G11 012974 0626 Rev. 07

Valid from: 2024-04-19

Valid until: 2026-12-14

Date of Initial Issuance: 2021-12-15

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-04-19



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. 08

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



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. 08

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

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



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. 08

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

**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