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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

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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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

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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

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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

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