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 IIa and Class IIb Devices)

No. G10 012974 0611 Rev. 09

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. 09

Report No.:	713308882
Preceding Certificate No.:	G10 012974 0611 Rev. 08
Valid from:	2024-05-28
Valid until:	2025-03-12
Date of Initial Issuance:	2020-03-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-05-28

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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. The system is used for the delivery of fluids indicated for infusion therapy.

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).

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

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

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:	-

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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:	-

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

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

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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.

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

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

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