





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 Ila

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, intraarterial, 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

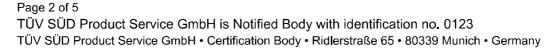
and their accessories.

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 / 7131884 21_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
80	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

