



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. 05

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 and certification regulation of 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. 05

Report No.:

713282403

Preceding Certificate No.:

G10 012974 0611 Rev. 04

Valid from:

2023-05-22

Valid until:

2025-03-12

Date of Initial Issuance:

2020-03-13

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2023-05-22

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No. G10 012974 0611 Rev. 05

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, 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).

Classification:

Class IIa

Device Group:

A010101 - HYPODERMIC NEEDLES

Intended Purpose:

Classification:

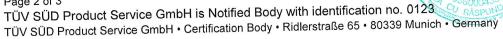
Class IIa

Device Group:

C010101 - PERIPHERAL I.V. CATHETERS

Intended Purpose:









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Classification:

Class IIa

Device Group:

A070199 - ADAPTERS AND CONNECTORS - OTHER

Intended Purpose:

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 |

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