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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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 023355 0023 Rev. 04

**Manufacturer:**

**Barkey GmbH & Co. KG**
Im Leuschnerpark 2
64347 Griesheim
GERMANY

SRN Manufacturer - DE-MF-000005854

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 023355 0023 Rev. 04

| | |
|---|---|
| **Report No.:** | 713368485_713345709 |
| **Preceding Certificate No.:** | G10 023355 0023 Rev. 03 |
| **Valid from:** | 2025-06-05 |
| **Valid until:** | 2027-05-12 |
| **Date of Initial Issuance:** | 2022-05-13 |

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2025-06-05


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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## No. G10 023355 0023 Rev. 04

| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | Z12019008 - BLOOD HEATERS<br>Z12019009 - THAWING UNITS<br>Z12019099 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY - OTHER |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z12019008 - BLOOD HEATERS |
| **Intended Purpose:** | Medical device is intended for heating of blood or infusions |

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

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2022-05-13 | 713201097 | - |
| 01 | 2023-04-17 | 713255777 | Supplemented: Device(s)/group of device(s) added |
| 02 | 2023-04-19 | 713255775 | Supplemented: Device(s)/group of device(s) added |
| 03 | 2023-11-02 | 713255773 | Supplemented: Device(s)/group of device(s) added |
| 04 | 2025-06-05 | 713368485_713345709 | Amended: Change of certificate holder's data |


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