# EU Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX, Chapters I and III

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

**curea medical GmbH**
**Münsterstraße 61-65**
**48565 Steinfurt**
**Germany**

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 of 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 conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. For devices of class IIb and IIa 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.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

For the placing on the market of class III devices and class IIb implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

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|---|---|
| **Single Registration Number of the Manufacturer (SRN):** | DE-MF-000006805 |
| **Authorised Representative:** | see Section 1 |
| **Limitations and Conditions:** | see Section 2 |
| **List of Products, Risk Classification and Details:** | see Section 3 |
| **Certificate History:** | see Section 4 |

| | | | |
|---|---|---|---|
| Certificate number: | 44 911 222190 | Valid from: | 2025-11-10 |
| Certification decision report No.: | 3535 5457 | Valid until: | 2030-11-09 |
| | | First issued: | 2025-11-10 |
| | | Issue date: | 2025-11-10 |
| | | Edition: | 1 |

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

TÜV NORD CERT GmbH
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TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-095

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Annex IX, Chapters I and III
Certificate number: 44 911 222190

## Section 1, Authorised Representative

| | |
|---|---|
| **Company name:** | N/A |
| **Street, No.:** | |
| **Postal Code, City:** | |
| **Country:** | |

## Section 2, Limitations and Conditions

| | |
|---|---|
| **The validity of this Certificate depends on:** | N/A |
| **and the following conditions:** | None |
| **and / or is limited to the following:** | N/A |

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Section 3, List of Products, Risk Classification and Details

**CLASS IIB**

| | |
|---|---|
| **Generic device group (EMDN):** | M040499<br><br>DEVICES FOR GENERAL AND SPECIALIST DRESSINGS |
| **TD assessment report no.:** | 3535 5514 |
| **Devices or groups of devices:** | Wound dressings curea P1<br>Wound dressings curea P1 drain<br>Wound dressings curea P1 duo<br>Wound dressings curea P1 heel<br>Wound dressings curea P1 easy<br>Wound dressings curea P1 border<br>Wound dressings curea P1 duo active<br>Wound dressings curea active 1<br>Wound dressings curea P2<br>Wound dressings curea P2 active<br>Wound dressings curea P1 easy border |
| **Intended use:** | Sterile care of injured skin where the dermis<br>has been breached and which requires secondary wound healing |

**CLASS I, DEVICES IN STERILE CONDITION**

| | |
|---|---|
| **Sterilisation method:** | Ethylene oxide gas sterilisation (EOG) |
| **Assessment report no.:** | 3537 3441 |
| **Devices or groups of devices:** | Liquisorb absorbent mat |

For class Is devices placed on the market in a sterile condition, the involvement of the notified body in the conformity assessment procedure is limited to those aspects related to the manufacture, securing and maintenance of sterile conditions.

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Section 4, Certificate History

| Edition | Date | Action leading to revision | Certification decision report No. |
|---|---|---|---|
| 1 | 2025-11-10 | Initial certification | ZA 3535 5457 |

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