

# EU Quality Management System Certificate

We hereby certify the company

**Beurer GmbH**  
**Söflinger Straße 218**  
**89077 Ulm**  
**Germany**

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

## **Annex IX – Chapter I (Quality Management System)**

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 3 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2025-11-24  
Valid until 2026-04-07

Registration No. D1311700064  
Report No. P25-00427-348546

Stuttgart, 2025-11-24



Notified Body



## Devices:

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Pulse oximeters

Risk class: IIa

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Blood pressure monitors

Risk class: IIa

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Thermometers

Risk class: IIa

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Bite healers

Risk class: IIa

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Massage devices

Risk class: IIa

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Hearing aids

Risk class: IIa

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Infrared lamps

Risk class: IIa

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Nebulizers

Risk class: IIa

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Daylight therapy lamps

Risk class: IIa

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TENS devices

Risk class: IIa

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Breast pumps electrical

Risk class: IIa

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Software modules for diagnostic purposes

Risk class: IIa

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ECGs

Risk class: IIa

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### The certificate is based on the previous certificate

D1311700046 (2021-04-08)  
D1311700049 (2021-07-28)  
D1311700052 (2022-03-30)  
D1311700054 (2023-03-14)  
D1311700055 (2023-08-14)  
D1311700058 (2024-02-12)  
D1311700063 (2025-07-28)

with the following changes to D1311700063:  
Supplemented by: ECGs