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	2025-07-28	Registration No.	D1311700063
Valid until	2026-04-07	Report No.	P24-01247-311356

Stuttgart, 2025-07-28

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Pulse oximeters

Risk class: IIa

Blood pressure monitors

Risk class: IIa

Thermometers

Risk class: IIa

Bite healers

Risk class: IIa

Massage devices

Risk class: IIa

Hearing aids

Risk class: IIa

Infrared lamps

Risk class: IIa

Nebulizers

Risk class: IIa

Daylight therapy lamps

Risk class: IIa

TENS devices

Risk class: IIa

Breast pumps electrical

Risk class: IIa

Software modules for diagnostic purposes

Risk class: IIa

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)

with the following changes to D1311700058:
Supplemented by Software modules for diagnostic purposes