

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 2024-02-12 Valid until 2026-04-07

Registration No. D1311700058 Report No. P20-00874-291482

Stuttgart, 2024-02-12

Notified Body



Registration No. D1311700058 Beurer GmbH | SRN: DE-MF-000005422

Devices:
Pulse oximeters Risk class: Ila
Blood pressure monitors Risk class: Ila
Infrared thermometers Risk class: Ila
Bite healers Risk class: Ila
Massage devices Risk class: Ila
Hearing aids Risk class: Ila
Infrared lamps Risk class: Ila
Nebulizers Risk class: Ila
Daylight therapy lamps Risk class: Ila

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TENS devices	
Risk class: Ila	
Breast pumps electrical	
Risk class: Ila	

The certificate is based on the previous certificate D1311700055 dated 2023-08-14 with the following changes:

Amended by the products: Breast pumps electrical; TENS devices