EU Technical Documentation Assessment Certificate

We hereby certify that the company

Beurer GmbH
Söflinger Straße 218
89077 Ulm
Germany

has submitted a technical documentation in accordance with Annexes II and III of Regulation (EU) 2017/746, which meets the following requirements:

Annex IX – Chapter II (Assessment of the Technical Documentation)

of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

Considering the specific requirements for devices for self-testing and near-patient testing of Section 5.1.

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

Valid from	2025-12-22	Registration No.	D1311700067
Valid until	2030-12-21	Report No.	P23-00906-272805

Stuttgart, 2025-12-22

Notified Body

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

Devices:

Blood glucose monitor: GL 44

Intended purpose: For use with the blood glucose monitoring kit GLMS 44

Risk class: C self-testing
IVS 1001 Devices intended to be used for near-patient testing
Basic UDI-DI: 4211125GL44NX

Control solution for Beurer blood glucose measurement devices: GLCS 3+4

Intended purpose: For use with the blood glucose monitoring kit GLMS 44

Risk class: C self-testing
IVS 1001 Devices intended to be used for near-patient testing
Basic UDI-DI: 4211125GLCS3+48K

Blood glucose monitoring kit: GLMS 44

Intended purpose: The GLMS 44 is a kit for the quantitative determination and regular monitoring of blood glucose values in humans. This determination is performed in fresh capillary and venous blood samples obtained from the fingertip.
The device is considered a therapy-accompanying diagnostic tool and must not be used for the diagnosis of diabetes mellitus or as the sole basis for therapy planning. For the initial evaluation of the measurement results and the selection and quantity of the required insulin, consultation with a physician is mandatory. For regular monitoring and continuous adjustment of the overall diabetes management, consultation with a medical contact is essential.
After the blood sample has been applied correctly, the evaluation takes place automatically.

Risk class: C self-testing
IVS 1001 Devices intended to be used for near-patient testing
Basic UDI-DI: 4211125GL44SystemT5

Blood glucose test strips for Beurer blood glucose measurement devices: GLTS 3+4

Intended purpose: For use with the blood glucose monitoring kit GLMS 44

Risk class: C self-testing
IVS 1001 Devices intended to be used for near-patient testing
Basic UDI-DI: 4211125GLTS3+4EE

Notes:

For the placing on the market of the devices an EU Quality Management System Certificate according to Annex IX, Chapter I of Regulation (EU) 2017/746 on in vitro diagnostic medical devices is also required.