beurer	Title	**EC Declaration of Conformity**
	Date	2025-12-04

Manufacturer:	Beurer GmbH (see address in footer)
SRN:	DE-MF-000005422.
Product category:	ECGs
Product type:	ME 95
Intended use:	The mobile ECG device provides information about the average pulse as well as changes in the heart rhythm. Using a Bluetooth® connection, the measurement data can be used by the doctor for an initial examination, but a diagnosis should not be made solely on the basis of the data but should be followed by further investigations. It is designed for self-measurement by adults in a domestic environment.

The product specified above is in conformity with the following specifications.

(EU) 2017/745	Medical device regulation (MDR)
Basic-UDI-DI:	4211125ME95PP
Classification/applied rule(s):	Class IIa/rule 10
Conformity assessment procedure:	Annex IX, Chapter I

The notified body mdc medical device certification GmbH, located at Kriegerstr. 6, 70191 Stuttgart, Germany, identification number 0483, issued in the course of the mentioned conformity assessment procedure the following certificate:

Certificate no. and validity:	D1311700064, valid to 2026-04-07

2014/53/EU	Radio equipment directive (RED) EN 50663:2017 EN 301 489-1 V.2.2.3(2019-11) EN 301 489-17 V.3.2.4 (2020-09) EN 300 328 V.2.2.2 (2019-07)
2011/65/EU	Restrictions of the use of certain hazardous substances in electrical and electronic equipment (RoHS) EN IEC 63000:2018

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of:	Beurer GmbH
Place, date of issue:	Ulm, 2025-12-04
Name, function, signature, stamp:	Werner Meternek, Director Quality Management & Regulatory Affairs ppa. Beurer GmbH Söflinger Straße 218 • 89077 Ulm