


beurer	Title	EC Declaration of Conformity
	Date	2026-04-02

Manufacturer:	Beurer GmbH (see address in footer)
SRN:	DE-MF-000005422
Product category:	Blood pressure monitors
Product type:	BM 28 (Model: Medel Sense)
Intended use:	The blood pressure monitor is intended for the fully automatic, non-invasive measurement of arterial blood pressure and pulse values on the upper arm. 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:	4211125BM28N3
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:	D1311700065, valid to 2030-11-15

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, 2026-04-02
Name, function, signature, stamp:	Max Harder, Team Lead Regulatory Affairs  Beurer GmbH Söflinger Straße 218 • 89077 Ulm