

beurer	Title	EC Declaration of Conformity
	Date	2025-12-08

Manufacturer:	Beurer GmbH (see address in footer)
SRN:	DE-MF-000005422
Product category:	Pulse oximeters
Product type:	PO 35
Intended use:	The pulse oximeter is used for non-invasive measurement of arterial oxygen saturation (SpO ₂) and heart rate (pulse rate) at home and in hospitals (not in AP and APG-class rooms). This device is not suitable for long-term measurement.
The product specified above is in conformity with the following specifications.	

(EU) 2017/745	Medical device regulation (MDR)
Basic-UDI-DI:	4211125PO35RC
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

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, 2025-12-08
Name, function, signature, stamp:	Werner Meternek, Director Quality Management & Regulatory Affairs
	 