

	Title	EC Declaration of Conformity
	Date	2024-11-18

Manufacturer: Beurer GmbH (see address in footer)
Product category: Blood pressure monitor
Product type: BC 28 (Model: BC 1 R VITAL+)
 The product specified above is in conformity with the following specifications.

93/42/EEC Medical device directive (MDD)
UMDNS code and name: 16-174 Blood Pressure Monitor, electronic, manual
Classification/applied rule(s): Class IIa/rule 10
Conformity assessment procedure: Annex II - excluding section 4
 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: D1311700043, valid to 2024-05-26
 EN 60601-1:2006 + A1:2013 + A11:2011 + A12:2014
 EN 60601-1-2:2015
 IEC 80601-2-30:2009 + A1:2013
 EN 1060-1:1995 + A2:2009
 EN 1060-3:1997 + A2:2009
 EN 1060-4:2004

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, 2024-11-18
Name, function, signature, stamp: Daniel Kämmerer, Team Lead Regulatory Affairs
