

EC Declaration of Conformity Title

File BM 57 EC DoC Beurer 20201005

Manufacturer:

Beurer GmbH (see address in footer)

Product category:

Blood pressure monitor

Product type:

BM 57

The product specified above is in conformity with the provisions of the following Union legislation and harmonized standards.

93/42/EEC

Medical device directive (MDD)

UMDNS code and name:

16-174 Blood Pressure Monitor, electronic, manual

Classification/applied rule(s):

Class Ila/rule 10

Conformity assessment

Annex VII in conjuction with annex V

procedure:

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:

D1311700038, valid to 2024-05-26

EN 60601-1:2006 + A1:2013

IEC 60601-1-2:2014

IEC 80601-2-30:2009 + A1:2013

EN ISO 81060-1:2012 EN 1060-3:1997 + A2:2009

2014/53/EU

Radio equipment directive (RED)

EN 62479:2010

EN 301 489-1 V2.1.1 (2017-02) EN 301 489-17 V3.1.1(2017-02) EN 300 328 V2.1.1 (2016-11)

2011/65/EU

Restrictions of the use of certain hazardous substances in electrical and electronic equipment (ROHS)

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, 05.10.2020

Name, function, signature,

Werner Meternek, Director R&D / RA

stamp:

Söflinger Straße 218 · 89077 Ulm