

Manufacturer: Beurer GmbH (see address in footer)

Product category: Pulse oximeter

Product type: PO 60

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: 17-148 Oximeter, Pulse

Classification/applied rule(s): Class IIb/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

IEC 60601-1:2012
IEC 60601-1-2:2014
ISO 80601-2-61:2011

2014/53/EU Radio equipment directive (RED)

EN 62479:2010
EN 301 489-1 V2.2.0 (2017-03)
EN 301 489-17 V3.2.0 (2017-03)
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, 13.05.2020

Name, function, signature, stamp: Werner Meternek, Director R&D / RA


Beurer GmbH
Springer Straße 218 • 89077 Ulm