

Manufacturer: Beurer GmbH (see address in footer)

Product category: Bite healer

Product type: BR 60 (Model: BR 58)

The product specified above is in conformity with the following specifications.

93/42/EEC Medical device directive (MDD)

UMDNS code and name: 15-610 Warming Units

Classification/applied rule(s): Class IIa/rule 9

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  
EN 60601-1-2:2015 + A1:2021

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, 2022-12-21

Name, function, signature, stamp: Daniel Kämmerer, Team Lead Regulatory Affairs



Beurer GmbH  
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