

Manufacturer: Beurer GmbH (see address in footer)

Product category: Hearing amplifier

Product type: HA 85

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: 11-967 Hearing Aids

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

Conformity assessment procedure: Annex VII in conjunction with annex V

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
EN 60601-2-66:2011
EN 60118-13:2005

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, 20.05.2021

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

i.v.  **Beurer GmbH**
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