

Title

EC Declaration of Conformity

File

HA 20_EC DoC_Beurer_20190709

Manufacturer:

Beurer GmbH (see address in footer)

Product category:

Hearing amplifier

Product type:

HA20

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 conjuction 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:

D1311700033, valid to 2023-07-02

EN 60601-1:2006 + A1:2013

EN 60601-2-66:2015 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, 09.07.2019

Name, function, signature,

stamp:

Daniel Kämmerer, Team Leader RA

Bettren GmbH Silvinger Straßt 218 89077 Um