

Title **EC Declaration of Conformity**

File IH 21-1_EC DoC_Beurer_20200622

Manufacturer:

Beurer GmbH (see address in footer)

Product category:

Nebulizer

Product type:

IH 21/1 (Model: IH 21)

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:

12-128 Nebulizer, Aerosol

Classification/applied rule(s):

Class Ila/rule 11

Conformity assessment

Annex II - excluding section 4

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:

D1311700043, valid to 2024-05-26

IEC 60601-1:2012 EN 60601-1-2:2015

EN 13544-1:2007 + A1:2009

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, 22.06.2020

Name, function, signature,

Daniel Kammerer, Team Leader RA

stamp:

Beurer GmbH (Sötlinger Straße 218 · 89077 Ulm