

Title EC

EC Declaration of Conformity

Date

2023-11-20

Manufacturer: Beurer GmbH (see address in footer)

SRN: DE-MF-000005422

Product category: Nebulizer

Product type: IH 57

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

(EU) 2017/745 Medical device regulation (MDR)

Basic-UDI-DI: 4211125IH57P2

Classification/applied

rule(s):

Class IIa/rule 12

Conformity assessment

procedure:

Annex IX, Chapter I

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: D1311700055, valid to 2026-04-07

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, 2023-11-20

Name, function, signature,

stamp:

Werner Meternek, Director Quality Management & Regulatory Affairs

Beurer GmbH Sädinger Straße 218 · 89077 Ulm