

EC - DECLARATION OF CONFORMITY



No.: IH 18-1_CE_DoC, valid to 2019-07-02
Manufacturer: Beurer GmbH
Address: Söflinger Str. 218
89077 Ulm
Germany

Förderndes Mitglied der
Deutschen Hochdruckliga

Förderndes Mitglied der
Deutschen Diabetes Stiftung

This declaration of conformity is issued under our sole responsibility.

UMDNS code and name: 12-128 Nebulizer, Aerosol
Category code and category: 04 Electrical and mechanical medical devices
Classification Rule/ Class: Rule 11/ Class IIa
Product name: IH 18/1
Expiry Date: 2019-07-02

The object of the declaration described above is in conformity with the relevant Community harmonisation legislation:

Directives _Date of last revision: CD 93/42/EEC (MDD) amended with 2007/47/EEC_2010-03-21
CD 2012/19/EC (WEEE)_2012-07-04
Reg. No.: DE 96226384
CD 2011/65/EC (ROHS)_2011-06-08

Conformity assessment procedure: Annex II – excluding Section 4 of CD 93/42/EEC (MDD)

Relevant harmonised standards: EN 60601-1: 2006 + A1: 2013
EN 60601-1-2: 2015
EN 13544-1: 2007 + A1: 2009

The notified body mdc - medical device certification GmbH, located at Kriegerstr. 6, D-70191 Stuttgart, identification number 0483, issued in the course of conformity assessment procedure the following certificate:

Certificate No._issued on: D1311700028_2017-11-29, valid to 2019-07-02
Signed for and on behalf of: Beurer GmbH
Place, date of issue: Ulm, 01.02.2019
Name, function and signature: Werner Meternek, Director R&D

Beurer GmbH
Söflinger Str. 218 89077 Ulm