HANS DINSLAGE GmbH Title EC Declaration of Conformity

File SIH 45_EC DoC_Hans Dinslage_2020-11-06

Manufacturer:

Hans Dinslage GmbH (see address in footer)

Product category:

Nebulizer

Product type:

SIH 45

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

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:

D1326900032, valid to 2024-05-26

EN 60601-1:2006 / A12:2014

IEC 60601-1-2:2014

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:

Hans Dinslage GmbH

Place, date of issue:

Ulm, 06.11.2020

Name, function, signature,

stamp:

Daniel Kämmerer, Team Leader RA

Hans Dinslage GmbH Riedlinger Str. 28 & 88524 Uttenweiler