CmbU	Title	EC Declaration of Conformity
	File	SIH 21-2_EC DoC_Hans Dinslage_20210413

Manufacturer: Hans Dinslage GmbH (see address in footer)

Product category: Nebulizer

Product type: SIH 21/2

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 IIa/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: D1326900034, 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: Hans Dinslage GmbH

Place, date of issue: Ulm, 13.04.2021

Name, function, signature,

stamp:

Daniel Kämmerer, Team Leader RA
Hans Dinslage GmbH

Riedlinger Str. 28 • 88524 Uttenweiler