

HANS DINSLAGE GmbH	Title	EC Declaration of Conformity
	Date	2025-10-23

Manufacturer: Hans Dinslage GmbH (see address in footer)

SRN: DE-MF-000005488

Product category: Nebulizers

Product type: SIH 21/2 (Model: SIH 21)

Intended use: Nebulizers (including compressor, ultrasonic, and mesh nebulizers) are medical devices for the nebulization of liquids and liquid medication (aerosols). This device produces aerosols by combining compressed air and liquid medication. The aerosol treatment is suitable for treating the upper and lower airways. By nebulizing and inhaling the medication prescribed / recommended by your doctor, you can prevent diseases affecting the airways, or in the case that you contract such an illness, you can alleviate symptoms and speed up your recovery.

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

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

Basic-UDI-DI: 4066299SIH21/2QR

Classification/applied rule(s): Class IIa/rule 12 and rule 20

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: D1326900049, valid to 2026-04-08

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: Hans Dinslage GmbH

Place, date of issue: Ulm, 2025-10-23

Name, function, signature, stamp: Werner Meternek, Director Quality Management & Regulatory Affairs

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