

DECLARATION OF CONFORMITY TO REGULATION(EU) 2017/745 ON MEDICAL DEVICES



CONTEC MEDICAL SYSTEMS CO., LTD.
No.112 Qinhuang West Street, Economic & Technical
Development Zone, Qinhuangdao, Hebei Province,
PEOPLE' S REPUBLIC OF CHINA

SRN of Manufacturer:CN-MF-000007715



Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf, Germany

SRN of Authorised Representative:DE-AR-000005129

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.
We keep all supporting documentation and ensure that the authorised representative has the
necessary documentation permanently available.

Basic UDI-DI:	69450401NE-M01BK
Product and Trade Name:	Mesh Nebulizer
EMDN Code:	Z12040210
Catalogue Number/model:	NE-M01/ NE-M01L
Risk Class of the Device:	Class IIa according to Annex VIII rule 20

We, (CONTEC MEDICAL SYSTEMS CO., LTD.) herewith declare that the stated medical
devices meet REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE
COUNCIL of 5 April 2017 on medical devices.

The harmonised standards and/or CS used and in relation to this conformity see annex.

NOTIFIED BODY:	TÜV SÜD Product service GmbH
	Ridlerstr 65, D-80339 München, Germany
NOTIFIED BODY IDENTIFICATION NUMBER:	0123

CONFORMITY ASSESSMENT PROCEDURE:	Regulation (EU) 2017/745, Annex IX excluding chapter II
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(EC) CERTIFICATE(S): G15 050972 0058 Rev. 00

PLACE, DATE OF ISSUE: Qinhuangdao, 2025/05/16

NAME AND FUNCTION, SIGNATURE: HUKUN,Chairman/ manufacturer

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Appendix: list of (harmonised - EN) standards

No.	Standards	Title and Description
1	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
3	EN 60601-1:2006/A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	EN 60601-1-2:2015/A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5	EN 60601-1-11:2015/A1:2021	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
6	EN13544-1:2007+A1:2009	Respiratory therapy equipment Part 1:Nebulizing system and their components
7	EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
8	EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
9	EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
10	ISO 15223-1:2021/Amd 1:2025	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
11	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
12	EN ISO 18562-1:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
13	EN ISO 18562-2:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
14	EN ISO 18562-3:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)
15	EN ISO 18562-4:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate
16	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer