


**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES**

MANUFACTURER:	CONTEC MEDICAL SYSTEMS CO., LTD No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	MESH NEBULIZER, NE-M01
CLASSIFICATION - ANNEX IX:	Class II a, Rule 11
CONFORMITY ASSESSMENT ROUTE:	Annex II excluding chapter 4
WE, (CONTEC MEDICAL SYSTEMS CO., LTD) HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.	
STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.	
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER:	CE 0123
(EC) CERTIFICATE(S):	<u>G1 050972 0050 Rev.03</u>
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2019/11/07 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2019/11/07
SIGNATURE:	 President

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Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
3	IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	IEC60601-1-2:2014	Medical electrical equipment- Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
5	IEC 60601-1-11:2015	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	IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
8	IEC 62366-1:2016	Medical devices - Application of usability engineering to medical devices
9	IEC 62304:2015	Medical device software-Software life-cycle processes
10	ISO15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
11	EN ISO10993-1: 2009 /AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
12	EN 1041: 2008	Information supplied by the manufacturer with medical devices