EC DECLARATION OF CONFORMITY

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Name and address of the manufacturer:	GuangZhou AXD Electronic Co., Ltd. Factory 3, No.9 Changxin Road, Changshapu, Zhongluotan Town, 510550, Baiyun District, Guangzhou City, Guangdong Province, P.R.China
Name and address of the European Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany

We declare under our sole responsibility that

the medical device:	Medical Compressor Nebulizer including (Product Name) AXD-301, AXD-302, AXD-303, AXD-305, AXD-307, AXD-308 (Model Designation)
of class:	IIa according to rule 11 in annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure:	**Directive 93/42/EEC Annex V**
Registration No.:	**FI21/07010**
Notified Body:	**SGS Fimko Ltd.** **Takomotie 8, FI-00380 Helsinki, Finland** **CE0598**

Guangzhou, May 21, 2021
Place, date

General Manager
Name and function

Applied Standards are listed as below:

No.	Standard No.	Standard Description
1	EN ISO 13485:2016	Medical devices – Quality management systems - Requirements for regulatory purposes
2	EN 60601-1:2006+A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
3	EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
4	EN 13544-1:2007+A1:2009	Respiratory therapy equipment Part 1: Nebulizing system and their components
5	EN 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	EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
7	EN ISO 10993-1:2009+AC:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
8	EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
9	EN ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
10	EN 60601-1-6:2010+A1:2015	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
11	EN 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices
12	EN 1041:2008+A1: 2013	Information supplied by the manufacturer of medical devices
13	EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
14	ISTA 2A:2011	Performance Test for Packaged-Products weighing 150 lb (68 kg) or Less