

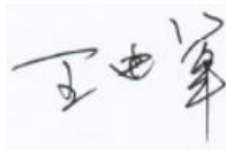
File name: Declaration of Conformity

File No.: AIDISY-UN-CE-02

Device Name: Portable (Ultrasonic) Nebulizer

Model: MESH-S600A, MESH-S600B,
MESH-S600C, MESH-S600D

Signature:



Date: 2021-05-15

Title: General Manager

Manufacturer:



Dongguan Aidisy Machinery & Electronic Equipment Co.,Ltd.

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Device name: Portable (Ultrasonic) Nebulizer

Model: MESH-S600A, MESH-S600B, MESH-S600C, MESH-S600D

Classification: II a (rule 11 of Annex IX of MDD 93/42/EEC)

UMDNS: 12719

GMDNS: 12719

Conformity assessment route: Annex V of MDD 93/42/EEC.

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards and laws of Sweden. All supporting documentations are retained under the premises of the manufacturer and notify body.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) and amended by directive 2007/47/EC.

On the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast): DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011.

Standard list:

EN ISO 13485:2016
EN ISO 15223-1:2016
EN 1041:2008
EN ISO 10993-1:2018
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN ISO 14971:2012
EN 60601-1:2006/A1:2013 EN 60601-1-2:2015
EN 60601-1-6:2010
EN 60601-1-11:2015 EN13544-1:2007+A1:2009 EN 62304:2006/AC: 2008
EN 62366-1:2015
EN ISO 780:2015

The above mentioned declaration of conformity is issued under the sole responsibility of

Company: Dongguan Aidisy Machinery & Electronic Equipment Co.,Ltd.

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(EC) Certificate: CN19/41056

Identification number of notified body: 1639

Expiration date of the Certificate: 11 May 2021 until 24 May 2024