NTLD

HONSUN(NANTONG)CO.,LTD

Version: E
Chapter: 01

DECLARATION OF CONFORMITY

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Manufacturer: HONSUN (Nantong) Co., Ltd.

SRN number CN-MF-000009428

Address: No.8, Tongxing Road, Economic&Technical Development

Area, Nantong City, Jiangsu, P.R.China

EU representative: Shanghai International Holding Corp. GmbH (Europe)

SRN number DE-AR-000000001

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product: Compressor Nebulizer

UMDNS code: 12712

Basic UDI-DI 697038425NEBR9

Model Code: NB-210C/NB-211C/NB-212C/NB-213C/NB-215C/NB-218C

NB-219C/NB-220C/NB-221C/NB-222C/NB-223C/NB-918C/

NB-226C

Intended use This compressor nebulizer is a medical device that used to

aerosolize medications for inhalation by the patient to achieve the expected therapeutic effect. The device can be

used with adult or pediatric patients.

Conforming Assessment Route11: Annex V.3

Classification (MDD, Annex IX rule 11): II a

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable directives: Medical Device Directive: COUNCIL

DIRECTIVE 93/42/EEC.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339

München, Germany

Certificate: No. G2 074340 0015 Rev.01

Expiration date of the Certificate: 2024-05-26

Date CE mark was affixed: start of CE marking lot: 2010-07

Identifier of Notified Body: CE0123

Signature

Iris Du

Position

RA Manager

Place, Date: NANTONG, 2023-07