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**DICHIARAZIONE DI
CONFORMITA'**

**CONFORMITY
DECLARATION**

FORNITORE SUPPLIER	: EP SPA (VIA DEL COMMERCIO N1 TRAVAGLIATO (BS))
PRODOTTO PRODUCT TYPE	: AEROSOL THERAPY DEVICE (NEBULIZER)
MARCHIO BRAND	: Emed
MODELLO MODEL	: A1500
CARATTERISTICHE RATINGS	: 230V 50Hz CLASS IIA (RULE11)
LOTTO	: N/A

Complies with prescription of European Directive 93/42/CEE (updated with directive 2007/47/CE) and to standards:

EN 60601-1:2006+A1:2013+A12:2014
EN 60601-1-2:2015

General requirements of electromedical devices
General requirements for basically safety and essential performances – Collateral standard: Electromagnetic compatibility

EN 60601-1-6:2010+AMD1:2015

General requirements for basic safety and essential performance - Collateral standard: Usability

EN 62366-1:2015/AC:2016-09
EN 60601-1-11:2015

Application of Usability Engineering to medical devices
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

UNI ISO 14971:2019
UNI EN 13544 1-2:2007+A1:2009
EN 60529:1991/A2:2013/AC:2019-02)
EN ISO 15223-1:2016

Risk management requirements
Respiratory therapy equipment
Enclosure protection degrees
Symbology used for medical devices labeling

Ultime due cifre dell'anno in cui è stato apposto il marchio CE
Last two digits of the year in which the CE marking was affixed: 20

PLACE AND DATE

Travagliato, 24/11/2020

SIGNATURE AND STAMP

For EP/SpA

Renato Chiarini
President