



ELECTROMEDICAL EQUIPMENTS

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ISO 9001 – ISO 13485 CERTIFIED



Certificate ISO 9001 no. 800210
Certificate ISO 13485 no. 908016

DECLARATION OF CONFORMITY

Manufacturer: CA-MI snc

Address: Via Ugo La Malfa n°31

Equipment: Aerosol Therapy Equipment

Trade name, model: EOLO – REF RE 300400
DAILY – REF RE 300400/01

Intended purpose: The equipment is designed for easy transport and handling and is recommended for atomising antibiotics and bronchodilator drugs

Ratings: 230V / 50Hz 170VA

The above mentioned equipment is complying with the European Directives : Medical Devices Directive 93/42/EEC and following updating

The above mentioned equipment is complying with the European Standards:

Safety Std: EN 60601-1

EMC Std : EN 60601-1-2

Other Std : EN 13544-1

Addition Informations:

Mentioned equipment has been classified as Medical Device with risk class IIa according to the roles of Annex IX of 93/42/EEC Directive.

EC marking procedure has been carried out according to the provisions of Annex VII (Declaration of Conformità) and Annex V (EC Declaration of conformity – Production Quality Assurance) [Nemko AS Certificate no. EU0607403]

Notified Body: NEMKO AS
Gaustadallèen 30
N-0371 Oslo – Norway

CE 0470

Data di emissione: venerdì 21 luglio 2006

CA-MI snc
Il Legale Rappresentante L'Azienda
Mario Attolini