



ELECTROMEDICAL EQUIPMENTS

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**ISO 9001:2000 / ISO 13485:2003
CERTIFIED**

DECLARATION OF CONFORMITY

Manufacturer: CA-MI snc

Address: Via Ugo La Malfa n°31

Equipment: Surgical aspirator

Trade name, model: NEW ASKIR 20 – REF RE 310100/09
NEW ASKIR 20 – REF RE 310100/12

Intended purpose: Surgical aspirator to be used for the nasal aspiration, oral aspiration, tracheal aspiration of the body liquids (mucus or catarrh and blood) in the adult or in the children.

Ratings: 230V ~ / 50Hz 184VA

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 + Annex

EMC Std: EN 60601-1-2

Other Std : EN ISO 10079-1

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 conformità – Production Quality Assurance) [Nemko AS Certificate no. EU0411408]

Notified Body: NEMKO AS
Gautstadallèen 30
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President of the Company

Mario Attolini