



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 30 12V – REF RE 310150
NEW ASKIR 30 12V – REF RE 310150/02

Intended purpose: NEW ASKIR 30 12V is a aspirator working with 12V DC (autotration battery) to be used for the nasal aspiration, oral aspiration, tracheal aspiration of the body liquids (mucus, catarrh or blood) in the adult or in the children.

Ratings: 12V dc 40W

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 :2001

Other Std : EN ISO 10079-1
Regulation ECE R-10

Additional Informations:

Mentioned equipment has been classified as Madical Device with risk class IIa accordino to the roles of Annex IX of 93/42/EECDirective.

EC marking procedure has been carried out accordino to the provisions of Annex VII (Declaration of Conformità) and Annex V (EC Declaration of conformità – Production Quality Assurance) [Nemko AS Certificate no. EU0510403]

Notified Body: NEMKO AS
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President of the Company
Mario Attolini