



ELECTROMEDICAL EQUIPMENTS

Via Ugo La Malfa nr.31
43010 Pilastro (PR) ITALY
Tel. +39 0521 637133 - 631138 Fax. +39 0521 639041
P.IVA 00977090349
www.ca-mi.it



**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 230/12 V BR – REF RE 310200
NEW ASKIR 230/12V BR – REF RE 310200/01

Intended purpose: SURGICAL ASPIRATOR working with 230V ~ AC 12V DC mixed power supply.
Easily trasportable from one hospital ward to another, particularly suitable for tracheotomized patients, minor surgical applications and post - operative therapy at home to be used for the nasal aspiration, oral aspiration, tracheal aspiration of the body liquids (mucus or catarrh) in the adult or in the children.

Ratings: 230 V - 50Hz or Internally powered equipment (PB Battery 12V 3Ah)
or 12Vdc (1.9A) from car battery

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

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. EU0510402]

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

CE 0470

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President of the Company
Mario Attolini