



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: Manual aspirator

Trade name, model: NEW EMIVAC

Intended purpose: Manual aspirator to be used for the emergency field to be used for aspiration of the body liquids (mucus or catarrh and blood)

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:

Other Std : EN ISO 10079-2

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. EU0507405]

Notified Body: NEMKO AS
Gautstadallèen 30
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Date of issue: mercoledì 25 gennaio 2006

President of the Company

Mario Attolini