



## 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 HOSPIVAC 350 – REF RE 310356  
NEW HOSPIVAC 350 – REF RE 310356/01  
NEW HOSPIVAC 350 – RE 310357  
NEW HOSPIVAC 350 – REF RE 310357/06

**Intended purpose:** Surgical aspirator to be used for the aspiration of the body liquids (mucus or catarrh and blood).

**Ratings:** 230V ~ / 50Hz 230VA

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

#### Additional 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. EU0412401]

**Notified Body:** NEMKO AS  
Gautstadallèen 30  
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**CE 0470**

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President of the Company  
**Mario Attolini**