



## 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 400 – REF RE 310350  
NEW HOSPIVAC 400 – REF RE 310350/01  
NEW HOSPIVAC 400 – REF RE 310350/08  
NEW HOSPIVAC 400 – REF RE 310350/05  
NEW HOSPIVAC 400 – REF RE 310351  
NEW HOSPIVAC 400 – REF RE 310350/07  
NEW HOSPIVAC 400 – REF RE 310350/09  
NEW HOSPIVAC 400 – REF RE 310350/10  
NEW HOSPIVAC 400 – REF RE 310350/11

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

**Ratings:** 230V ~ / 50Hz 300VA

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

**EMC Std:** EN 60601-1-2 :2001

**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. EU0412402]

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

**CE 0470**

**Date of issue:** mercoledì 8 marzo 2006

CA-MI snc  
Il Legale Rappresentante L'Azienda  
Mario Attolini