



Italian
Medical
Touch

CA-MI snc
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ISO 9001 – ISO 13485 CERTIFIED



Certificate ISO 9001 no. 800210
Certificate ISO 13485 no. 908016

DECLARATION OF CONFORMITY

Manufacturer: CA-MI snc
Address: Via Ugo La Malfa n°31
Device: Incentive Spirometers
Trade name, model: PULMOGAIN – REF RE 400100
Intended purpose: Incentive Spirometers. Device to exercise the respiration through inspiration

With the present one attests that such device is in compliance with the MDD 93/42/CEE .

The mentioned device has been classified Medical Device with risk **I class the not sterile** in agreement to the rules of Attached the IX of the MDD 93/42/CEE.

EC marking procedure has been carried out according to the provisions of Annex VII (Declaration of Conformity)

Date of issued: lunedì 13 novembre 2006

Issued by
Quality Assurance Manager
Manuel Saccani

Verified by:
General Manager
Mario Attolini