



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:** PULMOVOL – REF RE 400200

**Intended purpose:** Incentive Spirometers. Pulmovol is a single patient medical device to incentive deep and prolonged inspiration in patients suffering from all kind of restrictive and/or obstructive respiratory diseases.

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