



# EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

**No. G2 063105 0047 Rev. 01**

**Manufacturer:**

**CA-MI S.R.L.**

Via Ugo La Malfa, 13  
Frazione Pilastro  
43013 Langhirano (PR)  
ITALY

**Product  
Category(ies):**

**Aerosol Therapy Equipment, Kits for Aerosol Therapy,  
Thermal Water Inhaler, Suction Unit, Surgical Suction  
Equipment, Breast Pump, Kit Accessory for Electric  
Breast Pump, Blood Pressure Monitor, Electronic  
Thermometer, Infrared Thermometer, Tens Device,  
Pulse Oximeter**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G2\\_063105\\_0047\\_Rev\\_01](http://www.tuvsud.com/ps-cert?q=cert:G2_063105_0047_Rev_01)

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**Date,** 2021-02-09

Christoph Dicks  
Head of Certification/Notified Body