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 CERTIFICATE ◆ CERTIFICADO ◆ ЦЕРТИФИКАТ ◆ 認證證書 ◆ CERTIFICATE ◆ CERTIFIKAT



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 www.zlg.de  
 ZLG-BS-244.10.08



Product Service

# 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. 00**

**Manufacturer:** **CA-MI S.R.L.**  
 Via Ugo La Malfa, 13  
 Frazione Pilastro  
 43013 Langhirano (PR)  
 ITALY

**Facility(ies):** 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 Ear 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. See also notes overleaf.

**Report No.:** ITA1319360

**Valid from:** 2019-10-01

**Valid until:** 2024-05-26

**Date,** 2019-10-01

**Stefan Preiß**  
 Head of Certification/Notified Body

