



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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