



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

Report No.: ITA1626749

Valid from: 2021-02-09

Valid until: 2024-05-26

Date, 2021-02-09

Christoph Dicks
Head of Certification/Notified Body



Certificate

No. Q5 063105 0045 Rev. 03

Holder of Certificate:



CA-MI S.R.L.

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

Certification Mark:



Scope of Certificate:

Design and development, production, service and sale of medical equipments for surgery (electrical and manual suction pumps), electric breast pumps, medical devices for breathing (aerosol therapy equipments and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (pulse oximeters, thermometers, blood pressure monitors, sphygmomanometer and stethoscopes), incentive spirometers and medical devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5_063105_0045_Rev_03

Report No.: ITA1885389

Valid from: 2022-08-02

Valid until: 2025-08-01

Date, 2022-08-02

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 063105 0045 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Design and development, production, service and sale of medical equipments for surgery (electrical and manual suction pumps), electric breast pumps, medical devices for breathing (aerosol therapy equipments and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (pulse oximeters, thermometers, blood pressure monitors, sphygmomanometer and stethoscopes), incentive spirometers and medical devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices.

CA-MI S.r.l.
Via Strada per Parma 34, Frazione Pilastro, 43013 Langhirano
(PR), ITALY

Warehouse of active and non-active non implantable medical devices and components used in production.

CA-MI S.r.l.
Via Ugo La Malfa 27, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Production of medical devices for surgery (electrical and manual suction pumps), warehouse of active and non-active non implantable medical devices and components used in production.

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