CA-MI srl
Via Ugo La Malfa 13 - Frazione: Pilastro - 43013 Langhirano (PR) Italia
Tel. +39 0521 637133 - +39 0521 631138 - Fax. +39 0521 639041
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Italian Medical Touch

M0510 – Edizione 3 del 08.07.2016

DICHIARAZIONE DI CONFORMITÁ / *EC DECLARATION OF CONFORMITY*

Apparecchiatura / *Equipment*	Termometro Clinico senza Mercurio / *Mercury Free Clinical Thermometer*
Nome commerciale, modello / *Trade name, model*	T-CLASSIC (REF TR 100200) / T-FLAP (REF TR 100300)
Destinazione d'uso / *Intended Use*	Termometro Mercury Free utile alla misurazione clinica della temperatura corporea quando posizionato in sito ascellare oppure orale o rettale. *Mercury Free thermometer useful for clinical measurement of body temperature when positioned in axillary, oral or rectal position.*
Lotto di produzione / *Lot nr. production*	.....

CA-MI Srl, con sede legale in Via Ugo La Malfa nr.13 – Frazione Pilastro, 43013 Langhirano (PR) Italia, fabbricante dei dispositivi denominati "TERMOMETRI CLINICI MERCURY FREE" dichiara sotto la propria responsabilità che i dispositivi oggetto soddisfano tutti i requisiti essenziali richiesti dall'Allegato I della Direttiva sui Dispositivi Medici 93/42/CEE, emendata dalla Direttiva 2007/47/CE / ***CA-MI S.r.l.** with registered office in Via Ugo La Malfa 13 – Frazione Pilastro, 43013 Langhirano (PR) Italy, manufacturer of "MERCURY FREE CLINICAL THERMOMETERS", declares under its own responsibility that the product is in accordance with the Essential requirements (Annex I) to the Medical Devices Directives 93/42/EEC and subsequent changes.*

- **Classe di rischio** Im in accordo alla regola 5 dell'Allegato IX della Direttiva 93/42/CEE e s.m.i / ***Risk Class** Im according to the rule 5 of Annex IX of 93/42/EEC and subsequent changes;*
- CA-MI si impegna a conservare e tenere a disposizione dell'Organismo Notificato e dell'Autorità Competente il fascicolo tecnico di prodotto, così come specificato ai punti 2 e 3 dell'Allegato VII della Direttiva 93/42/EEC, per 5 anni dall'ultima data di vendita del prodotto / *CA-MI is committed to preserve and make available to the Notified Body and Competent Authority the Technical File of the product, as specified in Sections 2 and 3 of Annex VII of Directive 93/42/EEC, for 5 years from the last date of sale of the product.*

Il dispositivo medico è conforme alle norme europee / *The above mentioned equipment is complying with the European Standards:*

Safety Standard	EMC Standard	Other Standard
		EN 12470-1

La Lista delle norme applicabili è archiviata all'interno del Technical File di riferimento alla sezione 6 "Lista Norme e Direttive Applicabili"
The list of applied rules is stored in the Technical File (reference to section 6 "List of Applicable Standards")

La procedura per la marcatura CE è stata eseguita in accordo alle prescrizioni dell'Allegato VII (Dichiarazione di conformità) e dell'allegato V (Dichiarazione di conformità CE – garanzia di qualità di produzione) - Certificato TÜV SÜD Product Service GmbH no. G2M 16 06 63105 044 valido fino al 01-12-2019. *EC marking procedure has been carried out according to the provisions of Annex VII (Declaration of Conformity) and Annex V (EC Declaration of conformity – Production Quality Assurance) - TÜV SÜD Product Service GmbH Certificate no. G2M 16 06 63105 044 valid until 01-12-2019.*

Validità della dichiarazione di conformità / *Validity of EC declaration of conformity: 01-12-2019*

Organismo Notificato / *Notified Body*	TÜV SÜD Product Service GmbH / Zertifizierstelle – Ridlerstrasse 65 / 80339 München – Germany CE 0123
Luogo e Data di emissione / *Place and Date of Issued:*	Langhirano (PR), 20/07/2016

Digitally signed by Granaci Boris
Date: 2023.07.03 15:11:59 EEST
Reason: MoldSign Signature
Location: Moldova

Redatta da / *Issued by*:
Quality Assurance Manager
Manuel Saccani

Verificata e Approvata da / *Verified and approved by*:
General Manager
Mario Attolini

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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. 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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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, Annex V
(Devices in class I with measuring function)

No. G2M 063105 0048 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):

Various canister, suction unit, aneroid sphygmomanometer and mercury free clinical thermometer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: ITA1319360M

Valid from: 2019-09-26
Valid until: 2024-05-26

Date, 2019-09-26

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 063105 0045 Rev. 03

Holder of Certificate: **CA-MI S.R.L.**

CA-MI

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

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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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