



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 063105 0045 Rev. 05

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, servicing and distribution of medical equipments for surgery (electrical and manual suction pumps) and related accessories, electric breast pumps and related accessories, medical devices for breathing (aerosol therapy equipments and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (thermometers, 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, Certification, Validation and Verification Regulations 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. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5_063105_0045_Rev.05)

Report No.:

ITA200220009818

Valid from:

2025-08-02

Valid until:

2028-08-01

Date,

2025-07-28

Christoph Dicks

Head of Certification/Notified Body



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D-ZM-11321-01-00



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No. Q5 063105 0045 Rev. 05

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **CA-MI S.r.l.**
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Design and development, production, servicing and distribution of medical equipments for surgery (electrical and manual suction pumps) and related accessories, electric breast pumps and related accessories, medical devices for breathing (aerosol therapy equipments and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (thermometers, 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.
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

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

CA-MI S.r.l.
Via Ugo La Malfa, 15, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

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

/



CERTIFICATO

Nr. 50 100 7022 Rev.010

SI ATTESTA CHE / THIS IS TO CERTIFY THAT

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

CA-MI S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

**VIA UGO LA MALFA - FRAZIONE PILASTRO 13
IT - 43013 LANGHIRANO (PR)**

SEDI OPERATIVE: VEDI ALLEGATO 1 / OPERATIONAL SITES: **SEE ANNEX 1**

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione e sviluppo, produzione, assistenza tecnica e commercializzazione di dispositivi medici per chirurgia e relativi accessori (aspiratori elettrici e non), tiralatte elettrici e relativi accessori, dispositivi medici per respirazione (aerosolterapia, inalatori termali) e relativi accessori, dispositivi medici per il monitoraggio di parametri fisiologici vitali (termometri), dispositivi medici per la ginnastica respiratoria, dispositivi medici per flebologia (calze medicali a compressione graduata). Distribuzione di dispositivi medici attivi e non attivi non impiantabili.
(IAF 19, 12, 29)

Design and development, production, servicing and distribution of medical equipment for surgery (electrical and manual suction pumps) and related accessories, electric breast pumps and related accessories, medical devices for breathing (aerosol therapy equipment and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (thermometers), incentive spirometers and devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices. (IAF 19, 12, 29)



00077

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / Validity

Dal / From: **2025-08-01**

Al / To: **2028-07-31**

Francesco Scarlata

Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione /
Issuing Date

2025-07-23

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2007-09-03

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"



ALLEGATO 1 AL CERTIFICATO NR 50 100 7022 Rev.010
ANNEX 1 TO CERTIFICATE NO 50 100 7022 Rev.010
pagina 1 di 2 / page 1 of 2

IL CERTIFICATO NR 50 100 7022 Rev.010 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N 50 100 7022 Rev.010 COVERS ALSO THE FOLLOWING OFFICES:

CA-MI S.r.l.

VIA UGO LA MALFA - FRAZIONE PILASTRO 13
IT - 43013 LANGHIRANO (PR)

Progettazione e sviluppo, produzione, assistenza tecnica e commercializzazione di dispositivi medici per chirurgia e relativi accessori (aspiratori elettrici e non), tiralatte elettrici e relativi accessori, dispositivi medici per respirazione (aerosolterapia, inalatori termali) e relativi accessori, dispositivi medici per il monitoraggio di parametri fisiologici vitali (termometri), dispositivi medici per la ginnastica respiratoria, dispositivi medici per flebologia (calze medicali a compressione graduata). Distribuzione di dispositivi medici attivi e non attivi non impiantabili.

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STRADA PER PARMA 34 - FRAZIONE PILASTRO
IT - 43013 LANGHIRANO (PR)

Magazzino di dispositivi medici attivi e non attivi non impiantabili e componenti utilizzati in produzione.

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



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Per l'Organismo di Certificazione
For the Certification Body
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Italia

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Magazzino di dispositivi medici attivi e non attivi non impiantabili e componenti utilizzati in produzione.

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

VIA UGO LA MALFA, 15 - FRAZIONE PILASTRO
IT - 43013 LANGHIRANO (PR)

Produzione di dispositivi medici per chirurgia (aspiratori elettrici e manuali), magazzino di dispositivi medici attivi non impiantabili e componenti utilizzati in produzione.

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



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