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. 04

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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

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), 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. 04

Report No.: ITA18853891S

Valid from: 2023-09-19
Valid until: 2025-08-01

Digitally signed by Granaci Boris
Date: 2025.07.25 16:18:37 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Date, 2023-09-19

Christoph Dicks
Head of Certification/Notified Body

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

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. 04

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), 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 non implantable medical devices and components used in production.

CA-MI S.r.l.
Via Ugo La Malfa, 15, 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.

/