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

Product Service

Certificate

No. Q5 063105 0045 Rev. 01

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

Digitally signed by Granaci Boris
Date: 2020.03.16 13:13:59 EET
Reason: MoldSign Signature
Location: Moldova

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production, sale and after-sales technical assistance of medical equipments for surgery (electrical and manual suction pumps), electric breast pumps, medical devices for breathing (aerosol therapy equipments and thermal water inhaler), medical devices for stimulation (tens) and related accessories. Placing on the market under its own name of devices for monitoring of vital physiological parameters (pulse oximeters, thermometers, blood pressure monitors, sphygmomanometer and stethoscopes), incentive spirometers, devices for phlebology (graduated compression medical stockings) and anti-decubitus mattress.**
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). See also notes overleaf.

Report No.: ITA1254731

Valid from: 2019-08-01
Valid until: 2022-07-31

Date, 2019-07-30

Stefan Preiß
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
TÜV SÜD

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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

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

Facility(ies) Scope:

CA-MI S.R.L.
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR), ITALIA
Design and development, production, sale and after-sales technical assistance of medical equipments for surgery (electrical and manual suction pumps), electric breast pumps, medical devices for breathing (aerosol therapy equipments and thermal water inhaler), medical devices for stimulation (tens) and related accessories. Placing on the market under its own name of devices for monitoring of vital physiological parameters (pulse oximeters, thermometers, blood pressure monitors, sphygmomanometer and stethoscopes), incentive spirometers, devices for phlebology (graduated compression medical stockings) and anti-decubitus mattress.
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

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