



Product Service

Certificate

No. Q5 063105 0045 Rev. 01

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

Certification Mark:



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 TUV SUD 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





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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:

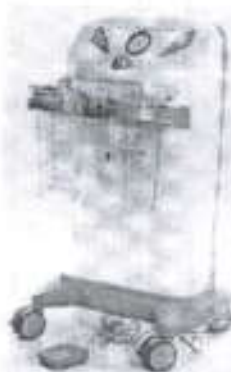
CA-MI S.R.L.
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR), ITALIA
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(graduated compression medical stockings) and anti-decubitus mattress.
Distribution of active and non-active non implantable medical devices.

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



ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFIKAT

New Hospivac 400 Operating Theatre suction units



Emergency Dept

Operating Theatre

General Surgery

Neurosurgery

Dental Practice

NEW HOSPIVAC 400 has been designed for professional aspiration of bodily fluids, gases, tissues or bones of the patient during or after surgery. The state-of-the-art oilless pump guarantees high performances with excellent suction capacities and max vacuum reachable within a few seconds, with no need for maintenance. A clear dashboard along with a full range of accessories makes it the ideal device for surgical suction.

● RE 410350

2 jars 2000 ml BASIC2

● RE 410350/09

2 jars 2000 ml + Footswitch FS2

● RE 410350/01

2 jars 2000 ml + Footswitch + Electronic Change-Over FULL2

● RE 410350/05

2 jars 4000 ml BASIC4

● RE 410350/10

2 jars 4000 ml + Footswitch FS4

● RE 410350/18

2 jars 4000 ml + Footswitch + Electronic Change-Over FULL4

● RE 410350/36

2 jars 5000 ml BASIC5

● RE 410350/37

2 jars 5000 ml + Footswitch FS5

● RE 410350/38

2 jars 5000 ml + Footswitch + Electronic Change-Over FULL5

with FLOVAC® Disposable Liners

● RE 410350/08

2 jars 2000 ml BASIC2

● RE 410350/03

2 jars 2000 ml + Footswitch FS2

● RE 410350/11

2 jars 2000 ml + Footswitch + Electronic Change-Over FULL2

● RE 410350/26

2 jars 2000 ml + Footswitch FS2

● RE 410350/27

2 jars 3000 ml BASIC3

● RE 410350/25

2 jars 3000 ml + Footswitch + Electronic Change-Over FULL3

Jars in APEC® autoclavable up to 143°C available upon request

Liquid Collection Jars with overflow valve system (SP.210006)

8x14 Silicone Tubes (autoclavable) + Conical Connector ø 10-11-12mm (RE.210355)

Antibacterial & Hydrophobic Filter (single-patient) SP.0047

Motor

Power Feeding

ISO 10079-1 Classification

Max free air flow rate

Max Vacuum (adjustable)

Noise level

Power consumption

Fuse

Duty cycle

Weight

Size

Years of Warranty

Place of Manufacturing

Oilless and maintenance-free piston pump

230V-50 Hz

HIGH VACUUM / HIGH FLOW

90 l/min

-0,90 Bar -90 kPa -675 mmHg

46,4dB

385 VA

1 x F4 A

Continuous

20 Kg

46x85x42 cm

2

ITALY

