Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD
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

Digitally signed by Cârstocea Ioan-Răzvan
Date: 2022.06.17 15:43:47 EEST
Reason: MoldSign Signature
Location: Moldova

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

CA-MI srl
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CA-MI Italian Medical Touch

M0510 – Edizione 3 del 08.07.2016

DICHIARAZIONE DI CONFORMITÁ / *EC DECLARATION OF CONFORMITY*

Apparecchiatura / *Equipment*	Aspiratori Chirurgici / *Surgical Suction Equipment*
Nome commerciale, modello / *Trade name, model*	NEW HOSPIVAC 350 (REF RE 410356) - NEW HOSPIVAC 350 (REF RE 410356/01) - NEW HOSPIVAC 350 (REF RE 410356/02) - NEW HOSPIVAC 350 (REF RE 410356/05) - NEW HOSPIVAC 350 (REF RE 410356/06) - NEW HOSPIVAC 350 (REF RE 410356/07) - NEW HOSPIVAC 350 (REF RE 410356/08) - NEW HOSPIVAC 350 (REF RE 410356/09) - NEW HOSPIVAC 350 (REF RE 410356/19) - NEW HOSPIVAC 350 (REF RE 410356/27) - NEW HOSPIVAC 350 (REF RE 410356/28) - NEW HOSPIVAC 350 (REF RE 410356/29) - NEW HOSPIVAC 350 (REF RE 410356/30) - NEW HOSPIVAC 350 (REF RE 410356/39) - NEW HOSPIVAC 350 (REF RE 410356/40) - NEW HOSPIVAC 350 (REF RE 410356/41) -
Destinazione d'uso / *Inteded Use*	Aspiratore chirurgico da utilizzarsi per l'aspirazione nasale, orale e tracheale nell'adulto o nei bambini di liquidi corporei (come ad esempio muco, catarro e sangue) / *Surgical aspirator to be used for the nasal aspiration, oral aspiration, tracheal aspiration of the body liquids (mucus or catarrh and blood) in the adult or in the children.*
Dati di targa / *Rating*	230V ~ / 50Hz 230VA
Lotto di produzione / *Lot nr. production*	....

CA-MI S.r.l., con sede legale in Via Ugo La Malfa n.13 – Frazione: Pilastro – 43013 Langhirano (PR) Italia, fabbricante dei dispositivi denominati "ASPIRATORI CHIRURGICI" 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 n.13 – Frazione: Pilastro – 43013 Langhirano (PR) Italy, manufacturer of "SURGICAL SUCTION EQUIPMENT", 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** IIa in accordo alla regola 11 dell'Allegato IX della Direttiva 93/42/CEE e s.m.i . ***Risk Class*** *IIa according to the rule 11 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 Europeans Standards:*

Safety Standard	EMC Standard	Other Standard
EN 60601-1	EN 60601-1-2	ISO 10079-1 / EN 60601-1-6 / EN 62366

La lista delle norme applicabili complete è archiviata all'interno del Technical File di riferimento alla sezione 6 "Lista Norme e Direttive Applicabili". *The list of complete 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. G2 063105 0047 Rev.00 valido fino al 26-05-2024. *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. G2 063105 0047 Rev.00 valid until 26-05-2024.* Validità della dichiarazione di conformità / *Validity of EC declaration of conformity: 26-05-2024*

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), 07/10/2019

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

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

TÜV SÜD
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

Certification Mark:

TÜV SÜD
EN ISO 13485
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®

A4 / 07.17

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

TÜV SÜD
Product Service

Certificate

No. Q5 063105 0045 Rev. 01

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

ON CASTORS SUCTION UNIT

NEW HOSPIVAC 350

with new **MPR system** Multi Purpose Rail

MAIN APPLICATIONS

- Emergency Dept.
- General Surgery
- Ginecology
- Neurosurgery
- Obstetrics
- Operating Theatre
- Dental Practice

CE 0123

Available in its three configurations, BASIC, FS and FULL, NEW HOSPIVAC 350 has been designed for professional aspiration of bodily fluids, tissues or bones of patients during or after surgery. The state-of-the-art 60 l/min oiless and maintenance-free pump provides high performances with excellent suction capacities and max vacuum built up within a few seconds. A clear dashboard along with a full range of accessories and antistatic castors with brakes make it the ideal device for surgical suction. The new MPR (Multi Purpose Rail) system enhances the versatility of the Hospivac series for easy and quick exchange of different accessories, with no need for tools. In fact, being equipped with five connections, all CA-MI accessories can be easily accommodated, such as rings of various diameters to fit jars of different sizes and types (2L, 3L, 5L), cannula holders or a medical stainless steel rail where to hook any other type of accessory by means of clamps. The new safety trap bottle is also a new standard accessory in the Hospivac series.
The new safety trap bottle is also a new standard accessory in the Hospivac series, bringing up to three the overflow protection systems, besides the valve integrated in the jar and the hydrophobic filter, thus providing the Hospivac series with the highest standards of safety.

AVAILABLE MODELS AND ACCESSORIES INCLUDED	BASIC	FS	FULL
Liquid Collection Jar with overflow valve system (different options, see below)	2	2	2
Rings to accommodate jars (3 sizes depending on the jar)	2	2	2
Safety Trap Bottle (220ml)	1	1	2
Antibacterial & Hydrophobic Filter (single-patient)	1	1	2
Silicone Tubes ø 8x14mm (autoclavable) - Patient Tube length 150cm	1	1	2
Conical Connector ø 10-11-12mm	1	1	2
Air suction inlet	1	1	2
Footswitch with intermittent or continuous operation		1	1
Change-Over System from jar to jar by soft-touch keys			1
Power Cord with Schuko plug	1	1	1

OPTIONAL ACCESSORIES

Rings available in three sizes:
- 2000 ml autoclavable jars
- 2000 ml and 3000 ml Flovac® disposable systems
- 5000 ml autoclavable jars

Cannula holder to store safely suction tube during operation
Footswitch with vacuum regulation function
Silicone Fetal Vacuum Cups
Standard medical stainless steel rail (25x10 or 30x10) and clamps

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	220-230V / 50-60Hz or 110-127V / 60Hz
Max Vacuum (adjustable)	-0.90 bar -90 kPa -675 mmHg (value at sea level - different altitudes may affect it)
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max free air flow rate	60 l/min
Noise Level	51,7 dBA
Duty cycle	Non-stop operation
Weight	20 kg (unit alone without accessories)
Size	cm 46 x 42 x 85
Years of Warranty	2
Shipping carton	1
Place of Manufacturing	Italy

Italian Medical Touch
MADE IN ITALY

(The warranty lapses immediately if the unit is used without all the required accessories or with non-original CA-MI accessories)

CONFIGURATIONS

NEW HOSPIVAC 350		AUTOCLAVABLE JARS						DISPOSABLE LINERS			
		Makrolon® 2858 (max 121°C)		Polysulfone (PSU)		Apec® (max 143°C)		Flovac® systems			
REF.	MODEL	2 Jars 2000 ml	2 Jars 5000 ml	2 Jars 2000 ml	2 Jars 5000 ml	2 Jars 2000 ml	2 Jars 5000 ml	2 Jars 2000 ml	2 Jars 3000 ml	FOOT SWITCH	CHANGE OVER
RE 410356	BASIC 2	■									
RE 410356/06	FS 2	■								■	
RE 410356/01	FULL 2	■								■	■
RE 410356/39	BASIC 5		■								
RE 410356/40	FS 5		■							■	
RE 410356/41	FULL 5		■							■	■
RE 410356/59	BASIC PSU 2			■							
RE 410356/60	FS PSU 2			■						■	
RE 410356/61	FULL PSU 2			■						■	■
RE 410356/62	BASIC PSU 5				■						
RE 410356/63	FS PSU 5				■					■	
RE 410356/64	FULL PSU 5				■					■	■
RE 410356/56	BASIC AP 2					■					
RE 410356/38	FS AP 2					■				■	
RE 410356/55	FULL AP 2					■				■	■
RE 410356/58	BASIC AP 5						■				
RE 410356/54	FS AP 5						■			■	
RE 410356/43	FULL AP 5						■			■	■
RE 410356/27	BASIC FLOVAC 2							■			
RE 410356/29	FS FLOVAC 2							■		■	
RE 410356/28	FULL FLOVAC 2							■		■	■
RE 410356/02	BASIC FLOVAC 3								■		
RE 410356/09	FS FLOVAC 3								■	■	
RE 410356/30	FULL FLOVAC 3								■	■	■

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CM005.REV6 EDITION NOVEMBER 2019