

NEW ASKIR 118 is an electric medical device for the nasal, oral and tracheal aspiration of body fluids in children or adults. It is available in two configurations, one specifically designed for use in ambulance car and emergency and the other for home-care and hospital applications. Large LCD for clear reading of vacuum values along with soft keys for vacuum adjustment increase the accuracy of aspiration. Smart operation thanks to the combination of the lightweight lithium-ion battery with the innovating FEEDBACK system that controls and manages the power of aspiration, providing a long autonomy of the battery and quiet noise level during operation. The PROXIMITY function to switch ON or OFF the device without touch prevents and avoids cross-contamination in-between patients. The unit is equipped with a long-life brushless motor eliminating any type of smell and coal residuals. The NEW ASKIR 118 series is available with various options of jar materials, such as the autoclavable polycarbonate (121°C), or the FLOVAC® disposable liners, or the APEC® that can resist up to 143°C. The ambulance wall mount is 10g dynamically tested according to the EN 1789:2007 last edition European Norm.

#### DIGITAL VERSION ACCESSORIES INCLUDED

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 8x14mm (autoclavable) Patient Tube length 150cm + Conical Connector ø 10-11-12mm
- Antibacterial & Hydrophobic Filter (single-patient) + CH20 Canula
- Universal switching power adapter (100-240V / 50-60Hz) and Cable
- 12V Car Adapter for RE410151/XX code only

BATTERY-OPERATED SUCTION UNIT

- Wall mount for ambulance (size cm 20x16x16) for RE410150/XX code only
- Protective Carrying Case (included for RE410150/XX / option for RE410151/XX code SP 0207/01)







#### **DIGITAL VERSION TECHNICAL FEATURES**

Brushless Motor —	Oiless and maintenance-free piston pump				
Power Feeding —	<ul> <li>14V 4A by AC/DC Universal Adapter 100-240V / 50-60Hz - 100VA (model UE60-140429SPA1)</li> <li>14,8V 5,2A Li-lon rechargeable battery - Autonomy 70 min Recharging Time 6 hours</li> </ul>				
	12V 4A Car adapter for RE410151/XX code only Wall mount for ambulance (12V 4A) for RE410150/XX code only				
	0.75 bar -75 kPa -563 mmHg (value at sea level - different altitudes may affect it)				
ISO 10079-1 Classification —	——— HIGH VACUUM / HIGH FLOW	1.1			
Max free air flow rate ———	26 l/min	Italian			
Noise level —	min. 46,7 dB max. 61,8 dB (depending on power supply)	HAHAH			
Duty cycle —	——— Non-stop operation (by mains only)	Medical			
IP Code	IP22	MEGICGI			
Weight	kg 4.07 (unit packed with all accessories)	Touch			
Size	cm 35 x 15 x 19	104611			
Years of Warranty —	2				
Shipping carton —	2	MADE IN ITALY			
Place of Manufacturing —	Italy				

DIGITAL VERSION AVAILABLE CONFIGURATIONS	ASKIR 118	ASKIR 118 WM
NEW ASKIR 118 with 1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 410151	RE 410150
NEW ASKIR 118 with 1000ml Autoclavable Jar in Apec®(max 143°C)	RE 410151/05	RE 410150/05
NEW ASKIR 118 with 1000ml Flovac®Disposable Liner	RE 410151/02	RE 410150/02



## SPARE ACCESSORIES

		ASPIRET ASKIR 20 ASKIR 30 ASKIR 230-12V BR ASKIR 30 12V	ASKIR 36 BR ASKIR 36 LI-ION ASKIR 118 ASKIR 118 BASIC	EMIVAC	ASKIR C30 ASKIR C30 BR	HOSPIVAC 350 HOSPIVAC 400 HOSPIVAC BR				
	SET of silicone TUBES, FILTERS and CONICAL CONNECTORS									
0	Tube Ø 6x10mm Conical connector	RE 210355		RE 210355/01						
	Tube Ø 6x10mm Conical connector Antibacterial filter	SP 0036		SP 0043						
and France	Tube Ø8 x 14 mm Conical connector		RE 210355/03		RE 210355/03	RE 210355/03				
	Tube Ø 8 x 14 mm Conical connector Antibacterial filter		SP 0036/02		SP 0036/02	SP 0032/01 (for 350 and BR) SP 0032 (for Hospivac 400)				
	FLOVAC® liners Tube Ø 6x10mm Conical connector	SP 0158/01								
A. A. A.	FLOVAC* liners Tube Ø 8x14mm Conical connector		SP 0160/01		SP 0160/01	SP 0160/01				
	Roll of silicone tube Ø 6x10 mm	Length $1m = SP 0045/02$ - Length $10m = SP 0045/03$ - Length $50m = SP 0045/04$ Length $1m = SP 0045/05$ - Length $10m = SP 0045/06$ - Length $50m = SP 0045/07$								
	Roll of silicone tube Ø 8X14 mm									
	MALE CONNECTORS									
STATE OF THE PARTY OF	Ø 8-9-10 mm (pack of 5's)	SP 0223	SP 0223		SP 0223	SP 0223				
	CONICAL CONNECTORS									
San Print	Ø 8-9-10 mm	RE 210410		RE 210410						
	Ø 10-11-12 mm		RE 210420		RE 210420	RE 210420				
	FILTERS (Antibacterial and Hydro	•								
	Ø 64 with 8 mm connector	SP 0046		SP 0046		CD 0101				
	Ø 64 with 11mm connector		SP 0121		SP 0121	SP 0121 (350 and BR only)				
	Ø 90 with 11mm connector					SP 0047 (for 400 only)				
	ASPIRATION PROBES									
	CH20	RE 210400 (10 pcs)	RE 210400 (10 pcs)		RE 210400 (10 pcs)					
	YANKAUER CANNULAS									
AL CONTRACTOR OF THE PARTY OF T	Yankauer Handle Flat Tip with Hole	2044403	2044403	2044403	2044403	2044403				
-	Yankauer Handle Crown Tip with Hole	2044401	2044401	2044401	2044401	2044401				
	Yankauer Tube L= 180	204413018	204413018	204413018	204413018	204413018				
	CATHETER CONTAINER									
=	Tube of polycarbonate Ø 54 mm by 400 mm length. Fully autoclavable (121°C - 15 min)					000032				
	SILICONE FETAL VACUUM CUP	S								
ŢŢŢ	Length 210 mm, Ø 50 mm, size XS				VC-95100	VC-95100				
	Length 210 mm, Ø 60 mm, size S				VC-95200	VC-95200				
	Length 210 mm, Ø 70 mm, size M				VC-95300	VC-95300				





## **EC** Certificate

Production Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)

No. G2 063105 0047 Rev. 01

Manufacturer: CA-MI S.R.L.

> Via Ugo La Malfa, 13 Frazione Pilastro 43013 Langhirano (PR)

**ITALY** 

**Product** Aerosol Therapy Equipment, Kits for Aerosol Therapy, Thermal Water Inhaler, Suction Unit, Surgical Suction Category(ies):

**Equipment, Breast Pump, Kit Accessory for Electric** Breast Pump, Blood Pressure Monitor, Electronic Thermometer, Infrared Thermometer, Tens Device,

**Pulse Oximeter** 

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. 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:G2 063105 0047 Rev. 01

ITA1626749 Report No.:

Valid from: 2021-02-09 Valid until: 2024-05-26

Date, 2021-02-09

Christoph Dicks

Head of Certification/Notified Body







**Product Service** 

## **Certificate**

No. Q5 063105 0045 Rev. 03

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, 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 and stethoscopes), 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: <a href="https://www.tuvsud.com/ps-cert?q=cert:Q5-063105-0045-Rev.-03">www.tuvsud.com/ps-cert?q=cert:Q5-063105-0045-Rev.-03</a>

Report No.: ITA1885389

 Valid from:
 2022-08-02

 Valid until:
 2025-08-01

Date, 2022-08-02 Christoph Dicks

Head of Certification/Notified Body





#### Product Service

### **Certificate**

No. Q5 063105 0045 Rev. 03

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 and stethoscopes), 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.I.

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.

CA-MI S.r.I.

Via Ugo La Malfa 27, Frazione Pilastro, 43013 Langhirano (PR), ITALY

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

/



# CERTIFICATO

Nr. 50 100 7022 Rev.008

Si attesta che / This is to certify that

IL SISTEMA QUALITÀ DI THE QUALITY SYSTEM OF

CA-MI S.r.I.

SEDE LEGALE: / REGISTERED OFFICE:

VIA UGO LA MALFA 13 - FRAZIONE PILASTRO 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

Progettazione e sviluppo, produzione, assistenza tecnica e commercializzazione di dispositivi medici per chirurgia (aspiratori elettrici e non), tiralatte elettrici, dispositivi medici per respirazione (aerosolterapia, inalatori termali) e relativi accessori, dispositivi medici per il monitoraggio di parametri fisiologici vitali (pulsossimetri, termometri, misuratori della pressione elettronici e non), dispositivi medici per la ginnastica respiratoria e 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, service and sale of medical equipment for surgery (electrical and manual suction pumps), electric breast pumps, medical devices for breathing (aerosol therapy equipment and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (pulse oximeters, thermometers, blood pressure monitors, sphygmomanometer and stethoscopes), incentive spirometers and medical devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices (IAF 19, 12, 29)



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

Validità / Validity

AI / To:

Dal / From:

2025-07-31

2022-08-01

SGQ N° 049A

ACCREDIA 3

L'ENTE ITALIANO DI ACCREDITAMENTO

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC Signatory of EA, IAF and ILAC Mutual Recognition Agreements Francesco Scarlata

Direttore Divisione Business Assurance

Business Assurance Division Manager

Data emissione / Issuing Date

2022-07-31

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.008

ANNEX 1 TO CERTIFICATE NO 50 100 7022 Rev.008

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IL CERTIFICATO NR 50 100 7022 (ultima revisione applicabile) COPRE ANCHE LE SEGUENTI SEDI OPERATIVE

THE CERTIFICATE N 50 100 7022 (last version) COVERS ALSO THE FOLLOWING OFFICES:

# CA-MI S.r.I.

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

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

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VIA 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

# VIA UGO LA MALFA 27 - FRAZIONE PILASTRO IT - 43013 LANGHIRANO (PR)

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

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

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

Validità / Validity

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