SPARE ACCESSORIES

	ASPIRET ASKIR 20 ASKIR 30 ASKIR TWIN 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					
Tube Ø 6 x 10 mm Conical connector	RE 210355		RE 210355/01		
Tube Ø 6 x 10 mm Conical connector Antibacterial filter	SP 0036		SP 0043		
 Tube Ø 8 x 14 mm Conical connector		RE 210355/03		RE 210355/03	RE 210355/03 ("old" jar holder) *** (new MPR system)
 Tube Ø 8 x 14 mm Conical connector Antibacterial filter		SP 0036/02		SP 0036/02	"old" jar holder SP 0032/01 (for 350 and BR) SP 0032 (for Hospivac 400) new MPR system *** (for Hospivac 350) *** (for Hospivac 400)
 FLOVAC® liners Tube Ø 6 x 10 mm Conical connector	SP 0158/01				
FLOVAC® liners Tube Ø 8 x 14 mm 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				
Roll of silicone tube Ø 8X14 mm	Length 1m = SP 0045/05 - Length 10m = SP 0045/06 - Length 50m = SP 0045/07				
MALE CONNECTORS					
 Ø 8-9-10 mm (pack of 5's)	SP 0223	SP 0223		SP 0223	SP 0223
CONICAL CONNECTORS					
 Ø 8-9-10 mm	RE 210410		RE 210410		
Ø 10-11-12 mm		RE 210420		RE 210420	RE 210420
FILTERS (Antibacterial and Hydrophobic)					
 Ø 64 with 8 mm connector	SP 0046		SP 0046		
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)	
CATHETER CONTAINER					
 Tube of polycarbonate Ø 54 mm by 400 mm length. Fully autoclavable (121°C - 15 min)					000032
SILICONE FETAL VACUUM CUPS					
 Length 210 mm, Ø 50 mm, size XS				VC-95100	VC-95100
Length 210 mm, Ø [illegible] size S				VC-95200	VC-95200
Length 210 mm, Ø 70 mm, size M				VC-95300	VC-95300

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

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

Product Service

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 Category(ies):

Aerosol Therapy Equipment, Kits for Aerosol Therapy, Thermal Water Inhaler, Suction Unit, Surgical Suction 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

Report No.: ITA1626749

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

Date, 2021-02-09

Christoph Dicks
Head of Certification/Notified Body

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

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www.zlg.de
ZLG-BS-244.10.08

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

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

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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. 02

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). 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. 02

Report No.: ITA1620011

Valid from: 2021-03-25
Valid until: 2022-07-31

Date, 2021-03-25

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service

Certificate

No. Q5 063105 0045 Rev. 02

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, 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.

CA-MI S.r.l.
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.

/

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