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

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 063105 0049 Rev. 00

Manufacturer:

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

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G2 063105 0047 Rev. 01

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply.

Report No.: ITA1885389

Valid until: 2024-05-26

Issue Date: 2022-08-02

Christoph Dicks
Head of Certification/Notified Body

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Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 063105 0049 Rev. 00

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**

Description of Change:

"Removal of product category "TENS DEVICE" from EC Certificate G2 063105 0047 rev.01 with related removal from Appendix A/B/C MEDF0315.01 of following product codes:

- **Medical device for stimulation (tens). MY TENS (REF TE 100100) last batch lot produces 1909C161 (2019 year)**
- **Medical device for stimulation (tens). Micro Tens (REF TE 100100/01) last batch lot produces 1412C53 (2014 year)"**

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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

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Add value.
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CA-MI S.r.l.
Via Ugo La Malfa, 13
Frazione Pilastro
43013 LANGHIRANO (PR)
ITALY

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
63105	ITA1816546_CL | 713264114	medical_devices@tuvsud.com	N/A	2024-05-16	1 of 10

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 063105 0053 Rev. 00

Reference: ITA1816546_CL | 713264114

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: **IT-MF-000020076**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CL 063105 0053 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,

16th May 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 895651
Riccardo Cottone

Riccardo Cottone
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Tunde Junaid
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BUDI: 8054610910R060101T3 **Article Number:** REF RE 300300; REF RE 300300/09; REF RE 300300/01; REF RE 300300/02; REF RE 300300/05; REF RE 300300/06; REF RE 300300/12; REF RE 300300/13; REF RE 300300/15; REF 01200; REF RE 300350; REF RE 300350/01	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: 8054610910Z120105WL **Article Number:** REF RE 310001; REF RE 310001/01; REF RE 310001/14; REF RE 310001/06; REF RE 310001/19; REF RE 310002; REF RE 310002/01; REF RE 310001/07; REF RE 310001/13; REF RE 310001/15; REF RE 310001/16; REF RE 310001/17; REF RE 310001/18; REF RE 310100/02; REF RE 310100/03; REF RE 310100/18; REF RE 310100/21; REF RE 310100/30; REF RE 310100/40; REF RE 310100/53; REF RE 310100/55; REF RE 310100/56; REF RE 310100/57; REF RE 310100/62; REF RE 310100/63; REF RE 310100/68; REF RE 310100/69; REF RE 310100/71; REF RE 310100/74; REF RE 310100/75; REF RE 310100/76; REF RE 310100/77; REF RE 310100/78; REF RE 310100/79; REF RE 310101/02; REF RE 310101/03; REF RE 310101/04; REF RE 310101/07; REF RE 310101/08; REF RE	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
310100/12; REF RE 310100/13; REF RE 310100/46; REF RE 310100/58; REF RE 310100/64; REF RE 310100/66; REF RE 310100/67; REF RE 310100/72; REF RE 310100/70; REF RE 310101/12; REF RE 310101/13; REF RE 410100; REF RE 410100/01; REF RE 410100/04; REF RE 410100/26; REF RE 410120; REF RE 410120/01; REF RE 410120/25; REF RE 310211; REF RE 310211/01; REF RE 310211/02; REF RE 310211/03; REF RE 310211/04; REF RE 310211/06; REF RE 310211/08; REF RE 310211/09; REF RE 310211/10; REF RE 310211/11; REF RE 310211/12; REF RE 310211/13; REF RE 310211/14; REF RE 310211/15; REF RE 410220; REF RE 410220/02; REF RE 410200/03; REF RE 410200/09; REF RE 410200/13; REF RE 410200/14; REF RE 410200/05; REF RE 410200/06; REF RE 410200/07; REF RE 410200/10; REF RE 410200/11; REF RE 410200/12; REF RE 410201; REF RE 410201/01; REF RE 410201/04; REF RE 410201/05; REF RE 410210/01; REF RE 410210/02; REF RE 410210/03; REF RE 410210/04; REF RE 410205; REF RE 410205/01; REF RE 410205/02; REF RE 410205/03; REF RE 410205/04; REF RE 410205/05; REF RE 410205/06; REF RE 410205/07; REF RE 410205/08; REF RE 410205/09; REF RE 410205/10; REF RE 410205/11; REF RE 410150; REF RE 410150/01; REF RE 410150/02; REF RE 410150/05; REF RE 410151; REF RE 410151/01; REF RE 410151/02; REF RE 410151/05; REF RE 410170; REF RE 410170/01; REF RE 410170/02;			

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
REF RE 410170/03; REF RE 410171; REF RE 410171/01; REF RE 410171/02; REF RE 410171/03; REF RE 410171/04; REF RE 410171/06; REF RE 410171/05; REF RE 410171/07; REF RE 310150/02; REF RE 310150/05;			
BUDI: 805461910R06992S **Article Number:** **REF DN 100100; REF DN 100100/02; REF DN 100100/03**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: **805461910V03010102V9** **Article Number:** REF TR 200050/01; REF TR 200030; REF TR 200030/01; REF TR 200040; REF TR 200040/01; REF TR 200300; REF TR 200300/01; REF TR 200300/02	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: **805461910Z120105MXH** **Article Number:** REF RE 310300	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
BUDI: 805461910Z120105PXP **Article Number:** REF RE 410250; REF RE 410250/01; REF RE 410250/10; REF RE 410250/14; REF RE 410250/15; REF RE 410250/16; REF RE 410251; REF RE 410251/01; REF RE 410251/03; REF RE 410251/04; REF RE 410251/05; REF RE 410251/06; REF RE 410400; REF RE 410400/01; REF RE 410400/02; REF RE 410400/03; REF RE 410350; REF RE 410350/01; REF RE 410350/09; REF RE 410350/36; REF RE 410350/37; REF RE 410350/38; REF RE 410350/05; REF RE 410350/10; REF RE 410350/18; REF RE 410350/08; REF RE 410350/03; REF RE 410350/11; REF RE 410350/27; REF RE 410350/28; REF RE 410350/25; REF RE 410350/40; REF RE 410350/33; REF RE 410350/46; REF RE 410350/48; REF RE 410350/39; REF RE 410350/47; REF RE 410350/13; REF RE 410350/41; REF RE 410350/49; REF RE 410350/55; REF RE 410350/56; REF RE 410350/50; REF RE 410350/51; REF RE 410350/63; REF RE 410350/64; REF RE 410350/57; REF RE 410350/58; REF RE 410350/59; REF RE 410350/60; REF RE 410350/61; REF RE 410350/62; REF RE 410350/35; REF RE 410350/30; REF RE 410350/32; REF RE 410350/43; REF RE 410350/44; REF RE	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
410350/45; REF RE 410350/65; REF RE 410350/66; REF RE 410350/67; REF RE 410350/68; REF RE 410350/69; REF RE 410350/70; REF RE 410350/71; REF RE 410350/72; REF RE 410356; REF RE 410356/06; REF RE 410356/01; REF RE 410356/39; REF RE 410356/40; REF RE 410356/41; REF RE 410356/05; REF RE 410356/07; REF RE 410356/08; REF RE 410356/27; REF RE 410356/29; REF RE 410356/28; REF RE 410356/02; REF RE 410356/09; REF RE 410356/30; REF RE 410356/56; REF RE 410356/38; REF RE 410356/55; REF RE 410356/58; REF RE 410356/54; REF RE 410356/43; REF RE 410356/57; REF RE 410356/25; REF RE 410356/26; REF RE 410356/32; REF RE 410356/34; REF RE 410356/36; REF RE 410356/37; REF RE 410356/44; REF RE 410356/46; REF RE 410356/47; REF RE 410356/48; REF RE 410356/49; REF RE 410356/50; REF RE 410356/51; REF RE 410356/52; REF RE 410356/53; REF RE 410356/59; REF RE 410356/60; REF RE 410356/61; REF RE 410356/62; REF RE 410356/63; REF RE 410356/64; REF RE 410356/65; REF RE 410356/66; REF RE 410356/67; REF RE 410356/68; REF RE 410356/69; REF RE 410356/70; REF RE 410356/71; REF RE 410356/72;			
BUDI: 805461910Z1208030303 **Article Number:** REF DC 620010; REF DC 620010/02	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
BUDI: 805461910Z120803994A **Article Number:** REF DC 520016	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: 805461910Z121590023V **Article Number:** REF RE 300200; REF RE 300200/02; REF RE 300230; REF RE 300230/01; REF RE 300240; REF RE 300240/01; REF RE 300250; REF RE 300250/03; REF RE 300250/04; REF RE 300250/05; REF RE 300250/06; REF RE 300250/08; REF RE 300250/11; REF RE 300400; REF RE 300400/15; REF RE 300400/05; REF RE 300430; REF RE 300450; REF RE 300550/03; REF RE 300551/03; REF RE 300550/02; REF RE 300560; REF RE 300600/03; REF RE 300600/12; REF RE 300600/15; REF RE 300600/17; REF RE 300600/18; REF RE 300700; REF RE 300700/04; REF RE 300400/07; REF RE 300400/12; REF RE 300400/16; REF RE 300600/08; REF RE 300600/11; REF RE 300230/02; REF RE 300240/03; REF RE 300240/02; REF RE 300240/04; REF RE 300250/10; REF RE 300230/03;	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BUDI: **805461910Z12159002IPT** **Article Number:** REF RE 420000; REF RE 420000/01; REF RE 320000; REF RE 320000/03; REF RE 320000/10	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: 805461910Z12159002MHPF **Article Number:** REF RE 300911; REF RE 300912; REF RE 300912/01; REF RE 300912/02; REF RE 300912/03	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: 805461910V03010199WJ **Article Number:** REF TR 100200; REF TR 100300; REF TR 100200/01; REF TR 100302; REF TR 100303; REF TR 100304; REF TR 100305; REF TR 100307; REF TR 100306	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☒ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2M 063105 0048 REV.00 NB#: 0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive: N/A

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable			

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/05/16	ITA1816546_CL | 713264114	Initial issue