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TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	CA-MI S.r.l.
Manufacturer address and contact details	Via Ugo La Malfa 13 – Frazione Pilastro 43013 Langhirano (PR) Italy e-mail: m.saccani@ca-mi.it
Single Registration Number (SRN) (if available)	IT-MF-000020076

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	TÜV SÜD PRODUCT SERVICE GMBH
Notified body number (if applicable)	0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	MDD 93/42/EEC Certificate No. G2M 063105 0048 Rev.00
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26/05/2024
End date of extended validity/transition period	31/12/2028

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☒ A QMS in accordance with Article 10(9) MDR is in place.
☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name:	CA-MI S.r.l.
Location & Date:	Langhirano (PR) Italy, 10.04.2024
Signature, Print Name, Title	Manuel Saccani (Quality Assurance / Person Responsible for Regulatory Compliance)

CA-MI S.r.l.
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Contact Details (at least email)	m.saccani@ca-mi.it / tecnico@ca-mi.it

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www.ca-mi.it - www.kamilamedical.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
T-CLASSIC (REF TR 100200)	MDD 93/42/EEC Certificate No. G2M 063105 0048 Rev.00 Families: Mercury Free Clinical Thermometer Budi: 8054610910V03010199WJ	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
T-VEDO (REF TR 100200/01)						
T-FLAP (REF TR 100300)						
TERMOMETRO CROWN (REF TR 100302)						
T-FLAP (REF TR 100303)						
KLASYK (REF TR 100304)						
T-GLASS (REF TR 100305)						
TERMO GREEN CLENNY (REF TR 100306)						
PRIMATHERM CLASSIC (REF TR 100307)						

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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 (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 063105 0047 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):

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 Ear 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. See also notes overleaf.

Report No.: ITA1319360

Valid from: 2019-10-01
Valid until: 2024-05-26

Date, 2019-10-01

Stefan Preiß
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®