REUSABLE JARS are equipped with screw cover with handle for easy grip, autoclavable silicone o-ring for tight seal, overflow valve system integrated in the cover, clear graduated scale in ml with 100ml or 200ml intervals, CA-MI branding. Suitable for central vacuum systems and CA-MI suction units.Available in two types of polycarbonate, Makrolon® and Apec®.

## REUSABLE JARS in MAKROLON® – FOR STEAM STERILIZATION UP TO 121 °C

| | Jar with: cover overflow valve o-ring | Jar | Cover with: overflow valve o-ring | O-ring | Suitable for: |
|---|---|---|---|---|---|
| 400 ml | RE 210301 | RE 210305 | RE 210302 | RE 210304 | EMIVAC |
| 1000 ml | RE 210001/02 | RE 210003 | RE 210352/01 | RE 210354 | ASPIRET<br>ASKIR series (all except C30 series)<br>Central Vacuum Plants |
| 2000 ml | RE 210351/01 | RE 210353 | RE 210352/01 | RE 210354 | ASPIRET - ASKIR Series<br>HOSPIVAC Series<br>Central Vacuum Plants |
| 4000 ml | RE 210006 | RE 210007 | RE 210008 | RE 210306 | HOSPIVAC Series<br>Vuoto centralizzato |
| 5000 ml | RE 210010 | RE 210013 | RE 210012 | RE 210307 | HOSPIVAC Series<br>Central Vacuum Plants |

## REUSABLE JARS in APEC® 1745 – FOR STEAM STERILIZATION UP TO 143 °C

| | Jar with: cover overflow valve o-ring | Jar | Cover with: overflow valve o-ring | O-ring | Suitable for: |
|---|---|---|---|---|---|
| 1000 ml | RE 210009 | RE 210002 | RE 210352/02 | RE 210354 | ASPIRET<br>ASKIR series (all except C30 series)<br>Central Vacuum Plants |
| 2000 ml | RE 210351/05 | RE 210353/01 | RE 210352/02 | RE 210354 | ASPIRET - ASKIR Series<br>HOSPIVAC Series<br>Central Vacuum Plants |
| 5000 ml | RE 210010/01 | RE 210013/01 | RE 210012/01 | RE 210307 | HOSPIVAC Series<br>Vuoto centralizzato |

FLOVAC® DISPOSABLE LINERS equipped with polyethylene disposable liner, hydrophobic filter, antibacterial filter, overflow system, reusable container with clear graduated scale in ml with 50ml intervals. The gelling kit is a powder inside liners with germicidal function turning the sucked liquid into a semisolid mass, preventing cross-contamination risks of staff in charge for hygiene and waste disposal.

## FLOVAC® DISPOSABLE LINERS & CONTAINERS

| | Liner with: cover filter | Liner with: cover filter gelling kit | Reusable Container | Suitable for |
|---|---|---|---|---|
| 1000 ml | 31848 | 31858 | 31843** | ASPIRET<br>ASKIR series (all except C30 series) |
| 1000 ml | 31845 | 31854 | 31840 | Central Vacuum Plants |
| 2000 ml | 31846 | 31855 | 31841 | ASPIRET - ASKIR Series<br>HOSPIVAC Series<br>Central Vacuum Plants |
| 3000 ml | 31847 | 31856 | 31842 | HOSPIVAC Series<br>Central Vacuum Plants |

** Requires additional round spacer (SP.0220) when ordered for ASKIR Series

Digitally signed by Grabazei Alexandru
Date: 2025.03.24 15:29:09 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

# SPARE ACCESSORIES

| | | ASPIRET<br>ASKIR 20<br>ASKIR 30<br>ASKIR 230-12V BR<br>ASKIR 30 12V | ASKIR 36 BR<br>ASKIR 36 LI-ION<br>ASKIR 118<br>ASKIR 118 BASIC | EMIVAC | ASKIR C30<br>ASKIR C30 BR | HOSPIVAC 350<br>HOSPIVAC 400<br>HOSPIVAC BR |
|---|---|---|---|---|---|---|
| | **SET of silicone TUBES, FILTERS and CONICAL CONNECTORS** | | | | | |
|  | Tube Ø 6x10mm<br>Conical connector | RE 210355 | | RE 210355/01 | | |
| | Tube Ø 6x10mm<br>Conical connector<br>Antibacterial filter | SP 0036 | | SP 0043 | | |
|  | Tube Ø 8 x 14 mm<br>Conical connector | | RE 210355/03 | | RE 210355/03 | RE 210355/03 |
|  | Tube Ø 8 x 14 mm<br>Conical connector<br>Antibacterial filter | | SP 0036/02 | | SP 0036/02 | SP 0032/01<br>(for 350 and BR)<br>SP 0032<br>(for Hospivac 400) |
|  | FLOVAC® liners<br>Tube Ø 6x10mm<br>Conical connector | SP 0158/01 | | | | |
| | FLOVAC® liners<br>Tube Ø 8x14mm<br>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<br>(350 and BR only) |
| | Ø 90 with 11mm connector | | | | | SP 0047<br>(for 400 only) |
| | **ASPIRATION PROBES** | | | | | |
|  | CH20 | RE 210400<br>(10 pcs) | RE 210400<br>(10 pcs) | | RE 210400<br>(10 pcs) | |
| | **YANKAUER CANNULAS** | | | | | |
|  | 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<br>by 400 mm length.<br>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 60 mm, size S | | | | VC-95200 | VC-95200 |
| | Length 210 mm, Ø 70 mm, size M | | | | VC-95300 | VC-95300 |

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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<br>43013 Langhirano (PR) Italy<br>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)<br>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) |

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| | |
|---|---|
| Contact Details (at least email) | m.saccani@ca-mi.it / tecnico@ca-mi.it |

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**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<br><br>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)

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# Manufacturer's Declaration

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- 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<br>43013 Langhirano (PR) Italy<br>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)<br>to which this confirmation is made (if applicable) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 |
| 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,

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  ☐ Expired *before* 20 March 2023:

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  ☐ 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, 04.04.2024 |
| Signature, Print Name, Title | Manuel Saccani (Quality Assurance / Person Responsible for Regulatory Compliance) |

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| | |
|---|---|
| Contact Details (at least email) | m.saccani@ca-mi.it / tecnico@ca-mi.it |

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Italian Medical Touch

**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) |
|---|---|---|---|---|---|---|
| COMPACT (REF RE 300200) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Aerosol Therapy Equipment<br>Budi: 805461091OZ121590023V | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| COMPACT (REF RE 300200/02) | | | | | | |
| MINIMAX (REF RE 300250) | | | | | | |
| ZEFIRO (REF RE 300250/03) | | | | | | |
| SIMPLE (REF RE 300250/04) | | | | | | |
| MINIMAX 2 (REF RE 300250/05) | | | | | | |
| MINIMAX (REF RE 300250/06) | | | | | | |
| MINIMAX COMBY (REF RE 300250/08) | | | | | | |
| SEA FAIR (REF RE 300250/11) | | | | | | |
| GEM (REF RE 300250/10) | | | | | | |
| PRONTEX FLOW (REF RE 300230) | | | | | | |
| FARMASOL (REF RE 300230/01) | | | | | | |
| ME 100 (REF RE 300230/02) | | | | | | |
| EVERCHECK NB200 (REF RE 300240/03) | | | | | | |
| KUBYNEB (REF RE 300240) | | | | | | |
| KUBYNEB (REF RE 300240/01) | | | | | | |
| EVERCHECK NB100 (REF RE 300240/02) | | | | | | |
| AEROPLUS (REF RE 300240/03) | | | | | | |
| ME 110 (REF RE 300240/04) | | | | | | |
| EOLO (REF RE 300400) | | | | | | |
| EOLO (REF RE 300400/05) | | | | | | |
| FLO-EOLO (REF RE 300400/15) | | | | | | |
| EOLO (REF RE 300400/07) | | | | | | |
| EOLO (REF RE 300400/12) | | | | | | |
| EOLO (REF RE 300400/16) | | | | | | |

[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)

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|---|---|---|---|---|---|---|
| PRONTEX WIND (REF RE 300430) | | | | | | |
| EVOLUTION (REF RE 300450) | | | | | | |
| MOBILE (REF RE 300700) | | | | | | |
| MOBILE (REF RE 300700/04) | | | | | | |
| CLINEB (REF RE 300550/03) | | | | | | |
| CLINEB BASIC (REF RE 300551/03) | | | | | | |
| AIR THERAPY (REF RE 300550/02) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Aerosol Therapy Equipment<br>Budi: 805461091OZ121590023V | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| CLINEB PRO (REF RE 300560) | | | | | | |
| MIKO (REF RE 300600/03) | | | | | | |
| MIKO BASIC (REF RE 300600/12) | | | | | | |
| BABY MIKO (REF RE 300600/08) | | | | | | |
| MIKO (REF RE 300600/11) | | | | | | |
| AIR PLUS 2000 (REF RE 300600/15) | | | | | | |
| AEROPHARMA (REF RE 300600/17) | | | | | | |
| MIKO (REF RE 300600/18) | | | | | | |
| KIWI PLUS (REF RE 300911) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Aerosol Therapy Equipment<br>Budi: 805461091OZ12159002MHPF | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| ONE PLUS (REF RE 300912) | | | | | | |
| ONE PRO (REF RE 300912/01) | | | | | | |
| AIREASY ON (REF RE 300912/02) | | | | | | |
| HI-FLO KIT (REF RE 300300/09) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Kits For Aerosol Therapy<br>Budi: 8054610910R060101T3 | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| HI-FLO KIT (REF RE 300300) | | | | | | |
| HI-FLO KIT (REF RE 300300/01) | | | | | | |
| HI-FLO KIT (REF RE 300300/02) | | | | | | |
| HI-FLO KIT (REF RE 300300/05) | | | | | | |
| HI-FLO KIT (REF RE 300300/06) | | | | | | |
| HI-FLO KIT (REF RE 300300/12) | | | | | | |
| SET ACCESSORI AEROSOLTERAPIA (REF RE 300300/13) | | | | | | |
| HI-FLO KIT (REF RE 300300/15) | | | | | | |
| PRONTEX AMPOLLA AEROSOL RAPID 2 (REF 01200) | | | | | | |

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|---|---|---|---|---|---|---|
| HI-4 KIT (REF RE 300350)<br>HI-4 + BOCCHERUOLA (REF RE 300350/01) | | | | | | |
| NASO-FREE (REF DN 100100)<br>RHINO CARE (REF DN 100100/02)<br>NASO-FREE (REF DN 100100/03) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br>Families: Kits For Aerosol Therapy<br>Budi: 8054610910R06992S | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW VAPINAL (REF RE 420000)<br>INALFAST (REF RE 420000/01)<br>NEW VAPINAL (REF RE 320000)<br>TERMALVAP (REF RE 320000/03)<br>INALPHARMA (REF RE 320000/10) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Thermal Water Inhaler<br>Budi: 80546109102121590002IPT | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW ASPIRET (REF RE 310001)<br>NEW ASPIRET (REF RE 310001/01)<br>NEW ASPIRET (REF RE 310002)<br>NEW ASPIRET (REF RE 310002/01)<br>NEW ASPIRET (REF RE 310001/07)<br>NEW ASPIRET (REF RE 310001/13)<br>NEW ASKIR 15 (REF RE 310001/15)<br>NEW ASKIR 15 (REF RE 310001/16)<br>NEW ASKIR 15 (REF RE 310001/17)<br>NEW ASKIR 15 (REF RE 310001/18)<br>KATASPIR 20 ECO (REF RE 310001/06)<br>LIFEMED 15 (REF RE 310001/14)<br>NEW ASPIRET (REF RE 310001/19) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 8054610910Z1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW ASKIR 20 (REF RE 310100/12)<br>NEW ASKIR 20 (REF RE 310100/13)<br>NEW ASKIR 20 (REF RE 310100/64)<br>NEW ASKIR 20 (REF RE 310100/70)<br>NEW ASKIR 20 (REF RE 310101/12)<br>NEW ASKIR 20 (REF RE 310101/13)<br>KATASPIR 20 (REF RE 310100/46) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 8054610910Z1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |

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|---|---|---|---|---|---|---|
| LIFEMED 20 (REF RE 310100/58) | | | | | | |
| NEW ASKIR (REF RE 310100/72) | | | | | | |
| TECNO 15 (REF RE 310100/66) | | | | | | |
| TECNO 15 (REF RE 310100/67) | | | | | | |
| NEW ASKIR 30 (REF RE 310100/02) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 8054610910Z1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW ASKIR 30 (REF RE 310100/03) | | | | | | |
| NEW ASKIR 30 (REF RE 310101/02) | | | | | | |
| NEW ASKIR 30 (REF RE 310100/53) | | | | | | |
| NEW ASKIR 30 (REF RE 310100/18) | | | | | | |
| NEW ASKIR 30 (REF RE 310100/30) | | | | | | |
| NEW ASKIR 30 (REF RE 310100/40) | | | | | | |
| NEW ASKIR 30 (REF RE 310100/63) | | | | | | |
| NEW ASKIR 30 (REF RE 310100/74) | | | | | | |
| NEW ASKIR (REF RE 310100/71) | | | | | | |
| KATASPIR 30 (REF RE 310100/21) | | | | | | |
| LIFEMED 40 (REF RE 310100/57) | | | | | | |
| TECNO 25 (REF RE 310100/68) | | | | | | |
| TECNO 25 (REF RE 310100/69) | | | | | | |
| NEW ASKIR 30 PROXIMITY (REF RE 310100/55) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 8054610910Z1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW ASKIR 30 PROXIMITY (REF RE 310100/56) | | | | | | |
| NEW ASKIR 30 PROXIMITY (REF RE 310100/62) | | | | | | |
| NEW ASKIR 30 PROXIMITY (REF RE 310100/75) | | | | | | |
| NEW ASKIR 30 PROXIMITY (REF RE 310100/76) | | | | | | |
| NEW ASKIR 30 PROXIMITY (REF RE 310100/77) | | | | | | |
| NEW ASKIR 30 PROXIMITY (REF RE 310100/78) | | | | | | |
| NEW ASKIR 30 PROXIMITY (REF RE 310100/79) | | | | | | |

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|---|---|---|---|---|---|---|
| NEW ASKIR 30 PROXIMITY (REF RE 310101/03) | | | | | | |
| NEW ASKIR 30 PROXIMITY (REF RE 310101/04) | | | | | | |
| NEW ASKIR 30 PROXIMITY (REF RE 310101/07) | | | | | | |
| NEW ASKIR 30 PROXIMITY (REF RE 310101/089 | | | | | | |
| AS-100 (REF RE 410100) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461091OZ1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| AS-100 (REF RE 410100/04) | | | | | | |
| ASPIMED 2.3 (REF RE 410100/26) | | | | | | |
| ACEEVAC SUC 81025 (REF RE 410100/01) | | | | | | |
| AS-200 (REF RE 410120) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461091OZ1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| AS-200 (REF RE 4101120/01) | | | | | | |
| ASPIMED 2.2 (REF RE 410120/25) | | | | | | |
| NEW ASKIR 230/12V BR (REF RE 310211) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461091OZ1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW ASKIR 230/12V BR (REF RE 310211/01) | | | | | | |
| NEW ASKIR 230/12V BR (REF RE 310211/03) | | | | | | |
| NEW ASKIR 230/12V BR (REF RE 310211/04) | | | | | | |
| NEW ASKIR 230/12V BR (REF RE 310211/06) | | | | | | |
| NEW ASKIR 230/12V BR (REF RE 310211/11) | | | | | | |
| NEW ASKIR 230/12V BR (REF RE 310211/12) | | | | | | |
| NEW ASKIR 230/12V BR (REF RE 310211/13) | | | | | | |
| NEW ASKIR 230/12V BR (REF RE 310211/14) | | | | | | |
| NEW ASKIR 230/12V BR (REF RE 310211/15) | | | | | | |
| NEW ASKIR 230/12V BR (REF RE 310211/10) | | | | | | |
| KATASPIR 230/12V BR (REF RE 310211/02) | | | | | | |
| TECNO 16B (111-A) (REF RE 310211/08) | | | | | | |
| TECNO 16B (114-A) (REF RE 310211/09) | | | | | | |
| AS-12VBR (REF RE 410200) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| ASPIMED 2.5 (REF RE 410200/02) | | | | | | |

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|---|---|---|---|---|---|---|
| | Budi: 805461091OZ1120105WL | | | | | |
| ASKIR 36BR (REF RE 410200/03) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461091OZ1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| ASKIR 36BR (REF RE 410200/09) | | | | | | |
| ASKIR 36BR (REF RE 410200/12) | | | | | | |
| ASKIR 36BR (REF RE 410200/13) | | | | | | |
| ASKIR 36BR (REF RE 410200/14) | | | | | | |
| ASKIR 36BR (REF RE 410200/10) | | | | | | |
| ASKIR 36BR (REF RE 410201) | | | | | | |
| ASKIR 36BR (REF RE 410201/01) | | | | | | |
| ASKIR 36BR (REF RE 410200/04) | | | | | | |
| NEW ASKIR 36BR (REF RE 410200/05) | | | | | | |
| NEW ASKIR 36BR (REF RE 410200/06) | | | | | | |
| NEW ASKIR (REF RE 410200/11) | | | | | | |
| KATASPIR 36BR (REF RE 410200/07) | | | | | | |
| AS-36BR (REF RE 410210/01) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461091OZ1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| AS-36BR (REF RE 410210/03) | | | | | | |
| AS-36BR (REF RE 410210/04) | | | | | | |
| CEEVAC SUC 81030 (REF RE 410210/02) | | | | | | |
| NEW ASKIR 36 LI-ION (REF RE 410205) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461091OZ1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW ASKIR 36 LI-ION (REF RE 410205/01) | | | | | | |
| NEW ASKIR 36 LI-ION (REF RE 410205/02) | | | | | | |
| NEW ASKIR 36 LI-ION (REF RE 410205/03) | | | | | | |
| NEW ASKIR 36 LI-ION (REF RE 410205/04) | | | | | | |
| NEW ASKIR 36 LI-ION (REF RE 410205/05) | | | | | | |
| NEW ASKIR 36 LI-ION (REF RE 410205/06) | | | | | | |
| NEW ASKIR 36 LI-ION (REF RE 410205/07) | | | | | | |
| NEW ASKIR 36 LI-ION (REF RE 410205/08) | | | | | | |
| NEW ASKIR 36 LI-ION (REF RE 410205/09) | | | | | | |
| NEW ASKIR 36 LI-ION (REF RE 410205/10) | | | | | | |
| NEW ASKIR 36 LI-ION (REF RE 410205/11) | | | | | | |

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|---|---|---|---|---|---|---|
| NEW ASKIR 118 (REF RE 410150) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 8054610910Z1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW ASKIR 118 (REF RE 410150/01) | | | | | | |
| NEW ASKIR 118 (REF RE 410150/02) | | | | | | |
| NEW ASKIR 118 (REF RE 410150/05) | | | | | | |
| NEW ASKIR 118 (REF RE 410151) | | | | | | |
| NEW ASKIR 118 (REF RE 410151/01) | | | | | | |
| NEW ASKIR 118 (REF RE 410150/02) | | | | | | |
| NEW ASKIR 118 (REF RE 410151/05) | | | | | | |
| NEW ASKIR 30 12V (REF RE 310150/02) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br>Families: Surgical Suction Equipment<br>Budi: 8054610910Z1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW ASKIR 30 12V (REF RE 310150/05) | | | | | | |
| NEW ASKIR 118 BASIC (REF RE 410171) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 8054610910Z1120105WL | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW ASKIR 118 BASIC (REF RE 410171/01) | | | | | | |
| NEW ASKIR 118 BASIC (REF RE 410171/02) | | | | | | |
| NEW ASKIR 118 BASIC (REF RE 410171/03) | | | | | | |
| NEW ASKIR 118 BASIC (REF RE 410171/04) | | | | | | |
| NEW ASKIR 118 BASIC (REF RE 410171/05) | | | | | | |
| NEW ASKIR 118 BASIC (REF RE 410171/06) | | | | | | |
| NEW ASKIR 118 BASIC (REF RE 410171/07) | | | | | | |
| NEW ASKIR 118 BASIC (REF RE 410170) | | | | | | |
| NEW ASKIR 118 BASIC (REF RE 410170/01) | | | | | | |
| NEW ASKIR 118 BASIC (REF RE 410170/02) | | | | | | |
| NEW ASKIR 118 BASIC (REF RE 410170/03) | | | | | | |
| ASKIR C30 (REF RE 410250) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461910Z120105PXP | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| ASKIR C30 (REF RE 410250/01) | | | | | | |
| ASKIR C30 (REF RE 410250/10) | | | | | | |
| ASKIR C30 (REF RE 410250/14) | | | | | | |
| ASKIR C30 (REF RE 410250/15) | | | | | | |
| ASKIR C30 (REF RE 410250/16) | | | | | | |
| ASKIR C30 BR | MDD 93/42/EEC Certificate | 26.05.2024 | TÜV SÜD | TÜV SÜD | 31.12.2028 | Not Applicable |

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|---|---|---|---|---|---|---|
| (REF RE 410251) | No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461910Z120105PXP | | PRODUCT SERVICE GMBH (0123) | PRODUCT SERVICE GMBH (0123) | | |
| ASKIR C30 BR (REF RE 410251/01) | | | | | | |
| ASKIR C30 BR (REF RE 410251/03) | | | | | | |
| ASKIR C30 BR (REF RE 410251/04) | | | | | | |
| ASKIR C30 BR (REF RE 410251/05) | | | | | | |
| ASKIR C30 BR (REF RE 410251/06) | | | | | | |
| NEW HOSPIVAC BR (REF RE 410400) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461910Z120105PXP | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW HOSPIVAC BR (REF RE 410400/01) | | | | | | |
| NEW HOSPIVAC BR (REF RE 410400/02) | | | | | | |
| NEW HOSPIVAC BR (REF RE 410400/03) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461910Z120105PXP | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW HOSPIVAC 400 (REF RE 410350/01) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/03) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/05) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/08) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/09) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/10) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/11) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/18) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/25) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/27) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/28) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/36) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/37) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/38) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/39) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/30) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/32) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/33) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/35) | | | | | | |
| NEW HOSPIVAC 400 | | | | | | |

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| **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) |
|---|---|---|---|---|---|---|
| (REF RE 410350/40) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/43) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/44) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/45) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/46) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/47) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/48) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/57) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/58) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/59) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/60) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/61) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/62) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/65) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/66) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/67) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/62) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/68) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/69) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/70) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/71) | | | | | | |
| NEW HOSPIVAC 400 (REF RE 410350/72) | | | | | | |
| LIFEMED 90 (REF RE 410350/13) | | | | | | |
| KYRI DSS (REF RE 410350/41) | | | | | | |
| TECNO 90 (REF RE 410350/55) | | | | | | |
| TECNO 90 (REF RE 410350/56) | | | | | | |
| TECNO 90 (REF RE 410350/49) | | | | | | |
| KATASPIR PRO (REF RE 410350/50) | | | | | | |
| KATASPIR PRO (REF RE 410350/51) | | | | | | |
| HiFlo2 – SUC 84602 (REF RE 410350/63) | | | | | | |
| HiFlo2 Max | | | | | | |

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| **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) |
|---|---|---|---|---|---|---|
| SUC 84604 (REF RE 410350/64) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410356) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461910Z120105PXP | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| 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 410356/27) | | | | | | |
| 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) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410356/38) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410356/43) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410356/54) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410356/55) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410356/56) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410356/58) | | | | | | |
| TECNO 40 (REF RE 410356/57) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/25) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/26) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/32) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/36) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/37) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/34) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/51) | | | | | | |

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| **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) |
|---|---|---|---|---|---|---|
| NEW HOSPIVAC 350 (REF RE 410350/52) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/53) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/44) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/46) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/47) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/48) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/49) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/50) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/51) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/52) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/53) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/59) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/60) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/61) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/62) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/63) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/64) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/65) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/66) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/67) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/68) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/69) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/70) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/71) | | | | | | |
| NEW HOSPIVAC 350 (REF RE 410350/72) | | | | | | |
| NEW EMIVAC (REF RE 310300) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Surgical Suction Equipment<br>Budi: 805461910Z120105MXH | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| NEW MAMILAT (REF DC 620010) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 | 26.05.2024 | TÜV SÜD PRODUCT SERVICE | TÜV SÜD PRODUCT SERVICE GMBH | 31.12.2028 | Not Applicable |
| NEW MAMILAT | | | | | | |

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| **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) |
|---|---|---|---|---|---|---|
| (REF DC 620010/02) | Families: Breast Pump<br>Budi: 80546191OZ12030303 | | GMBH (0123) | (0123) | | |
| SET ACCESSORI TIRALATTE ELETTRICO (REF DC 520016) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Kit for Electric Breast Pump<br>Budi: 805461910Z120803994A | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| CLIAMED TERMOMETRO ASCELLARE (REF TR 200050) | MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01<br><br>Families: Electronic Thermometer<br>Budi: 805461910V03010102V9 | 26.05.2024 | TÜV SÜD PRODUCT SERVICE GMBH (0123) | TÜV SÜD PRODUCT SERVICE GMBH (0123) | 31.12.2028 | Not Applicable |
| digiT-40 (REF TR 200030) | | | | | | |
| digiT-40 (REF TR 200030/01) | | | | | | |
| digiT-40F (REF TR 200040) | | | | | | |
| digiT-40F (REF TR 200040/01) | | | | | | |
| digiT-10P (REF TR 200300) | | | | | | |
| TERMO FLASH CLENNY (REF TR 200300/01) | | | | | | |
| T-Digit (REF TR 200300/02) | | | | | | |

Add value.
Inspire trust.

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:**<br>8054610910R060101T3<br><br>**Article Number:**<br>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<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2 063105 0047 REV. 01<br>NB#: 0123 |
| **BUDI:**<br>8054610910Z120105WL<br><br>**Article Number:**<br>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<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2 063105 0047 REV. 01<br>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:**<br>805461910R06992S<br><br>**Article Number:**<br>**REF DN 100100; REF DN 100100/02; REF DN 100100/03** | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2 063105 0047 REV. 01<br>NB#: 0123 |
| **BUDI:**<br>**805461910V03010102V9**<br><br>**Article Number:**<br>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<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2 063105 0047 REV. 01<br>NB#: 0123 |
| **BUDI:**<br>**805461910Z120105MXH**<br><br>**Article Number:**<br>REF RE 310300 | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2 063105 0047 REV. 01<br>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<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | | |
| **BUDI:**<br>805461910Z120105PXP<br><br>**Article Number:**<br>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<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2 063105 0047 REV. 01<br>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**<br><br>**Article Number:** REF DC 620010; REF DC 620010/02 | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2 063105 0047 REV. 01<br>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<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | | |
| **BUDI: 805461910Z120803994A**<br><br>**Article Number:**<br>REF DC 520016 | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2 063105 0047<br>REV. 01<br>NB#: 0123 |
| **BUDI: 805461910Z121590023V**<br><br>**Article Number:**<br>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<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2 063105 0047<br>REV. 01<br>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:**<br>**805461910Z12159002IPT**<br><br>**Article Number:**<br>REF RE 420000; REF RE 420000/01; REF RE 320000; REF RE 320000/03; REF RE 320000/10 | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2 063105 0047<br>REV. 01<br>NB#: 0123 |
| **BUDI:**<br>805461910Z12159002MHPF<br><br>**Article Number:**<br>REF RE 300911; REF RE 300912; REF RE 300912/01; REF RE 300912/02; REF RE 300912/03 | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2 063105 0047<br>REV. 01<br>NB#: 0123 |
| **BUDI:**<br>805461910V03010199WJ<br><br>**Article Number:**<br>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<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☐ Class IIa<br>☐ Class I devices in sterile condition<br>☒ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A | ☒ Certification as follows:<br>Certificate: G2M 063105 0048<br>REV.00<br>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 |

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. 03

**Holder of Certificate:** **CA-MI S.R.L.**

CA-MI

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: www.tuvsud.com/ps-cert?q=cert:Q5 063105 0045 Rev. 03

**Report No.:** ITA1885389

**Valid from:** 2022-08-02
**Valid until:** 2025-08-01

**Date,** 2022-08-02

Christoph Dicks
Head of Certification/Notified Body


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

TÜV®

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. 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.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.

/


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

TÜV®

Italia

# 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.l.

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.l.**

Validità /*Validity*

Dal / From: **2022-08-01**

Al / To: **2025-07-31**

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

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"*



ZERTIFIKAT ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT ◆ CERTIFICATE

Italia

**ALLEGATO** 1 AL CERTIFICATO NR **50 100 7022 Rev.008**
***ANNEX 1*** *TO CERTIFICATE NO* ***50 100 7022 Rev.008***


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.l.

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

*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*

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*

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

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

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

**Francesco Scarlata**
Direttore Divisione Business Assurance
*Business Assurance Division Manager*

Validità /*Validity*

Dal / From: **2022-08-01**

Al / To: **2025-07-31**

Data emissione /
*Issuing Date*

**2022-07-31**

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