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www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 049861 0158 Rev. 01

Manufacturer:

ResMed Pty Ltd
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153
AUSTRALIA

Product Category(ies): **Positive Airway Pressure Devices, Ventilators, Humidifiers, Masks, Tubes and associated Accessories, Patient Data Recorders (Respiratory).**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JAQ235040503**

Valid from: **2019-12-04**
Valid until: **2024-05-26**

Date, **2019-12-04**

Christoph Dicks
Head of Certification/Notified Body

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

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ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 049861 0158 Rev. 01

Facility(ies): **ResMed Pty Ltd**
1 Elizabeth Macarthur Drive, Bella Vista NSW 2153,
AUSTRALIA

-/-

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ResMed

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	**ResMed Pty. Ltd.**
Manufacturer address and contact details	**1 Elizabeth Macarthur Drive Bella Vista, NSW 2153 - Australia**
Single Registration Number (SRN) (if available)	**AU-MF-000011753**

Authorised Representative name (if applicable)	**ResMed SAS**
Authorised Representative address and contact details	**Parc Technologique de Lyon 292 Allée Jacques Monod, 69791 Saint Priest Cedex - France**
Single Registration Number (SRN) (if available)	**FR-AR-000007151**

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)	**G1 049861 0158**
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	**26 May 2024**
End date of extended validity/transition period	**31 December 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.

ResMed Pty Ltd
1 Elizabeth Macarthur Drive, Bella Vista NSW 2153, Australia

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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

ResMed Pty Ltd
1 Elizabeth Macarthur Drive, Bella Vista NSW 2153, Australia

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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 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.

➢ **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.

ResMed Pty Ltd
1 Elizabeth Macarthur Drive, Bella Vista NSW 2153, Australia

ResMed

Signed for and on behalf of the manufacturer:

Full Company	ResMed Pty. Ltd.
Location & Date	Sydney, Australia 24 May 2024
Signature, Print Name, Title	Nicole Wilson, Director Global Product Regulatory Affairs DocuSigned by: Nicole Wilson F9F55744DEA64A0...
Contact Details (at least email)	nicole.wilson@resmed.com.au

ResMed Pty Ltd
1 Elizabeth Macarthur Drive, Bella Vista NSW 2153, Australia

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)
38122- AIRMINI AUTOSET W EU	G1 049861 0158 Rev. 01	26 May 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	31 December 2028	N/A
27011 Astral 100 – EUR1 27013 Astral 150 – EUR1 27021 Astral 100 – EUR2 27023 Astral 150 – EUR2 27031 Astral 100 – EUR3 27033 Astral 150 – EUR3 27052 Astral 100 – DEU 27053 Astral 150 – DEU 27061 Astral 100 – EUR4 27063 Astral 150 – EUR4 27071 Astral 100 – FRA 27073 Astral 150 – FRA 27083 Astral 150 - APAC1 27088 Astral 150 - APAC2 27094 Astral 150 - APAC4						N/A
28113 Lumis 150 VPAP ST EUR1						N/A
23003 AcuCare HFNC - Small (20pk)						N/A

[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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23004 AcuCare HFNC-Medium (20pk) 23005 AcuCare HFNC - Large (20pk) 23006 ACUCARE HFNC - SMALL 23007 ACUCARE HFNC - MEDIUM 23008 ACUCARE HFNC - LARGE						
60759 NV AcuCare F1-0 FFM SML-EU1 20pk 60760 NV AcuCare F1-0 FFM MED-EU1 20pk 60761 NV AcuCare F1-0 FFM LGE-EU1 20pk 60786 NV AcuCare F1-0 FFM SML-EU1 5pk 60787 NV AcuCare F1-0 FFM MED-EU1 5pk 60788 NV AcuCare F1-0 FFM LGE-EU1 5pk 60971 NV ACUCARE F1-0 FFM SML-ROW 60972 NV ACUCARE F1-0 FFM MED-ROW 60973 NV ACUCARE F1-0 FFM LGE-ROW 60990 NV ACUCARE F1-0 FFM SML-ROW 5PK 60991 NV ACUCARE F1-0 FFM MED–ROW 5PK 60992 NV ACUCARE F1-0 FFM LGE-ROW 5PK						N/A
61032 Pixi Pediatric Mask-EUR3 61031 Pixi Pediatric Mask-EUR1, EUR2						N/A

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62100 Mirage FX Mask Sys-EUR1 62101 Mirage FX Mask Sys-EUR2 62102 Mirage FX Mask Sys-EUR3 62115 Mirage FX Mask Sys WD-EUR1 62116 Mirage FX Mask Sys WD-EUR2 62117 Mirage FX Mask Sys WD-EUR3 62132 Mirage FX for Her Mask Sys - EUR1 62133 Mirage FX for Her Mask Sys - EUR2 62139 Mirage FX for Her Mask Sys--EUR3						N/A
62782 NV Quattro Air FFM XSML - EUR 62783 NV Quattro Air FFM SML - EUR 62784 NV Quattro Air FFM MED - EUR 62785 NV Quattro Air FFM LGE - EUR						N/A
64020 AirFit F20 NV SML Sys ROW 64021 AirFit F20 NV MED Sys ROW 64022 AirFit F20 NV LGE Sys ROW 63447 AIRFIT F20 LGE SYS - SLM 63446 AIRFIT F20 MED SYS - SLM 63445 AIRFIT F20 SML SYS - SLM						N/A

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64114 AirFit F30 SML Sys MultiHole- EU 64110 AirFit F30 SML Sys - EU 64115 AirFit F30 MED Sys MultiHole- EU 64111 AirFit F30 MED Sys – EU 64105 AIRFIT F30 MED SYS - SLM 64104 AIRFIT F30 SML SYS - SLM						N/A
60762 NV AcuCare F1-1 FFM SML-EU1 20pk 60763 NV AcuCare F1-1 FFM MED-EU1 20pk 60764 NV AcuCare F1-1 FFM LGE-EU1 20pk 60789 NV AcuCare F1-1 FFM SML-EU1 5pk 60790 NV AcuCare F1-1 FFM MED-EU1 5pk 60791 NV AcuCare F1-1 FFM LGE-EU1 5pk 60974 NV ACUCARE F1-1 FFM SML-ROW 60975 NV ACUCARE F1-1 FFM MED-ROW 60976 NV ACUCARE F1-1 FFM LGE-ROW 60993 NV ACUCARE F1-1 FFM SML –ROW 5PK 60994 NV ACUCARE F1-1 FFM MED –ROW 5PK 60995 NV ACUCARE F1-1 FFM LGE– ROW 5PK						N/A
60765 AcuCare F1-4 FFM SML-EU1 20pk						N/A

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60766 AcuCare F1-4 FFM MED-EU1 20pk 60767 AcuCare F1-4 FFM LGE-EU1 20pk 60792 AcuCare F1-4 FFM SML-EU1 5pk 60793 AcuCare F1-4 FFM MED-EU1 5pk 60794 AcuCare F1-4 FFM LGE-EU1 5pk 60977 ACUCARE F1-4 FFM SML-ROW 60978 ACUCARE F1-4 FFM MED-ROW 60979 ACUCARE F1-4 FFM LGE-ROW 60996 ACUCARE F1-4 FFM SML-ROW 5PK 60997 ACUCARE F1-4 FFM MED-ROW 5PK 60998 ACUCARE F1-4 FFM LGE–ROW 5PK						
62704 Quattro Air FFM XSML-EUR1 62705 Quattro Air FFM SML-EUR1 62706 Quattro Air FFM MED-EUR1 62707 Quattro Air FFM LGE-EUR1 62709 Quattro Air FFM SML-EUR2 62710 Quattro Air FFM MED-EUR2 62711 Quattro Air FFM LGE-EUR2 62713 Quattro Air FFM SML-EUR3						N/A

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62714 Quattro Air FFM MED-EUR3 62715 Quattro Air FFM LGE-EUR3 62743 Quattro Air FFM for Her XSML-EUR1 62744 Quattro Air FFM for Her SML-EUR1 62745 Quattro Air FFM for Her MED-EUR1 62746 Quattro Air FFM for Her XSML-EUR2 62747 Quattro Air FFM for Her SML-EUR2 62748 Quattro Air FFM for Her MED-EUR2 62749 Quattro Air FFM for Her XSML-EUR3 62750 Quattro Air FFM for Her SML-EUR3 62751 Quattro Air FFM for Her MED-EUR3						
64001 NV ELBOW F20 ACCESSORY						N/A
38808 HUMIDX 50PK 38809 HumidX 3PK 38810 HumidX 6PK 38846 HumidX 38811 HumidX Plus 50PK 38812 HumidX Plus 3PK 38813 HumidX Plus 6PK 38847 HumidX Plus 38015 HUMIDX F20 38012 HUMIDX F20 3PK 38013 HUMIDX F20 6PK						N/A
36858 S9/AIR10 FILTER, HYPO, 50 PACK						N/A

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36856 S9/AIR10 FILTER, HYPO, 2 PACK 36857 S9/AIR10 FILTER, HYPO, 12 PACK 36855 S9/AIR10 FILTER, HYPO, 1 PACK 38857 AirMini Filter Hypo 2PK 38858 AirMini Filter Hypo 12PK						
27902 Remote Alarm II, ROW						N/A
24988 RESMED LEAK VALVE - ROW (DISP)						N/A
38823 N20 AIRMINI SETUP PACK 38825 F20 AIRMINI SETUP PACK 38010 F30 Airmini setup pack 38011 F20 AirMini Setup Pack + Humidx						N/A
38824 P10 AirMini Mask Pack						N/A
37357 ClimateLineAir Oxy 37296 ClimateLine Air						N/A
28403 Lumis HFT EUR2 28401 Lumis HFT EUR1						N/A
63516 AirFit N20 SML (for Her) - EU3 63513 AirFit N20 SML (for Her) - EU2 63510 AirFit N20 SML (for Her) - EU1 63509 AirFit N20 SML - EU1 63517 AirFit N20 MED Sys - EU3						N/A

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63514 AirFit N20 MED Sys - EU2 63511 AirFit N20 MED Sys - EU1 63518 AirFit N20 LGE Sys - EU3 63515 AirFit N20 LGE Sys - EU2 63512 AirFit N20 LGE Sys - EU1 63507 AIRFIT N20 LGE SYS - SLM 63506 AIRFIT N20 MED SYS - SLM 63505 AIRFIT N20 SML (FOR HER) - SLM 63504 AIRFIT N20 SML SYS - SLM						
63716 AirFit N20 CL SML Sys - EU3 63713 AirFit N20 CL SML Sys - EU2 63710 AirFit N20 CL SML Sys - EU1 63717 AirFit N20 CL MED Sys - EU3 63714 AirFit N20 CL MED Sys - EU2 63711 AirFit N20 CL MED Sys - EU1 63718 AirFit N20 CL LGE Sys - EU3 63715 AirFit N20 CL LGE Sys - EU2 63712 AirFit N20 CL LGE Sys - EU1						N/A
63910 AIRTOUCH N20 SML (FOR HER) - EU1						N/A

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63909 AIRTOUCH N20 SML - EU1 63911 AIRTOUCH N20 MED SYS - EU1 63912 AIRTOUCH N20 LGE SYS - EU1No						
22243 AirMini by ResMed IOS App 22244 AirMini by ResMed Android App						N/A
14922 AIR TUBING - Grey 3 Metre 14980 AIR TUBING - GREY 3 METRE 14994 Tubing, Clear-Gray Ribbed 6(1.83m) 36810 SLIMLINE TUBING 37394 Air10 Tubing Elbow 14948 GREY TUBING - CUFFED.STD TUBING 2M						N/A
61204 Mirage Quattro FFM XSML - EUR1 61205 Mirage Quattro FFM SML - EUR1 61206 Mirage Quattro FFM MED - EUR1 61207 Mirage Quattro FFM LGE - EUR1 61208 Mirage Quattro FFM XSML - EUR2 61209 Mirage Quattro FFM SML - EUR2 61210 Mirage Quattro FFM MED - EUR2 61211 Mirage Quattro FFM LGE - EUR2 61220 MIRAGE QUATTRO FFM XSML-FRA						N/A

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61221 MIRAGE QUATTRO FFM SML-FRA 61222 MIRAGE QUATTRO FFM MED-FRA 61223 MIRAGE QUATTRO FFM LGE-FRA 61228 Mirage Quattro FFM XSML - EUR3 61229 Mirage Quattro FFM SML - EUR3 61230 Mirage Quattro FFM MED - EUR3 61231 Mirage Quattro FFM LGE - EUR3						
61105 HOSPITAL NASAL MASK SYST LGE-ROW 61104 HOSPITAL NASAL MASK SYST MED-ROW						N/A
36996 ClimateLine Max Oxy 36997 CLIMATELINE MAX TUBING 36995 ClimateLine Tubing						N/A
24928 H4i for Stellar GERMANY 24929 H4i for Stellar EUR GP 1, UK 24930 H4i for Stellar EUR GP 2 24936 H4i for Stellar FRANCE						N/A
63822 SLM AIRFIT N30I SML STPK 63821 SLM AIRFIT N30I STD STPK 63871 SLM AIRFIT P30I STD STPK						N/A
60646 NV UMFFM SYS LGE SHW-EUR1						N/A

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60647 NV UMFFM SYS LGE STD-EUR1 60652 NV UMFFM SYS LGE STD-EUR2 60644 NV UMFFM SYS MED SHW-EUR1 60645 NV UMFFM SYS MED STD-EUR1 60650 NV UMFFM SYS MED STD-EUR2 60642 NV UMFFM SYS SML SHW-EUR1 60643 NV UMFFM SYS SML STD-EUR1 60648 NV UMFFM SYS SML STD-EUR2						
60153 Mirage Activa LT Mask LG-WD-EUR1 60151 Mirage Activa LT Mask MED - EUR1						N/A
62927 AirFit P10 for Her SYS - SLM 62925 AirFit P10 Mask SYSTEM - SLM						N/A
26960 ResMed Oxygen Connector Port						N/A
37299 HumidAir Standard Tub						N/A
27202 ResMed Connectivity Module EUR						N/A
27401 ResMed Connectivity Module Hospital ROW						N/A
25945 EasyCare TX 25922 EasyCare TX Web Delivery						N/A

ResMed Pty Ltd
1 Elizabeth Macarthur Drive, Bella Vista NSW 2153, Australia

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ResMed Pty Ltd
1 Elizabeth Macarthur Drive
2153 BELLA VISTA
AUSTRALIA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
049861	MDR CA: 73580288 MDR CNs: 713210119; 713259724; 713260923; 713295236; 713316588	Ting.Liu@tuvsud.com		2024-04-25	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 049861 0237 Rev. 00

Reference: 73580288 | 713210119 | 713259724 | 713260923 | 713295236 | 713316588

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: AU-MF-000011753

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.

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=cert:CL 049861 0237 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-25

TÜV SÜD Product Service GmbH
Medical and Health Services

Ting Liu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Apr 25, 2024 09:32 GMT+2)

Michael Mauermeir
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
38122 AIRMINI AUTOSET W EU	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
27011 Astral 100 – EUR1 27013 Astral 150 – EUR1 27021 Astral 100 – EUR2 27023 Astral 150 – EUR2 27031 Astral 100 – EUR3 27033 Astral 150 – EUR3 27052 Astral 100 – DEU 27053 Astral 150 – DEU 27051 Astral 100 SC – DEU 27061 Astral 100 – EUR4 27063 Astral 150 – EUR4 27071 Astral 100 – FRA 27073 Astral 150 – FRA 27083 Astral 150 - APAC1 27088 Astral 150 - APAC2 27094 Astral 150 - APAC4	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
28113 Lumis 150 VPAP ST EUR1	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
23003 AcuCare HFNC - Small (20pk) 23004 AcuCare HFNC-Medium (20pk) 23005 AcuCare HFNC -Large (20pk) 23006 ACUCARE HFNC - SMALL 23007 ACUCARE HFNC - MEDIUM 23008 ACUCARE HFNC - LARGE	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
60759 NV AcuCare F1-0 FFM SML-EU1 20pk 60760 NV AcuCare F1-0 FFM MED-EU1 20pk 60761 NV AcuCare F1-0 FFM LGE-EU1 20pk 60786 NV AcuCare F1-0 FFM SML-EU1 5pk 60787 NV AcuCare F1-0 FFM MED-EU1 5pk 60788 NV AcuCare F1-0 FFM LGE-EU1 5pk 60971 NV ACUCARE F1-0 FFM SML-ROW 60972 NV ACUCARE F1-0 FFM MED-ROW 60973 NV ACUCARE F1-0 FFM LGE-ROW 60990 NV ACUCARE F1-0 FFM SML-ROW 5PK 60991 NV ACUCARE F1-0 FFM MED ROW 5PK 60992 NV ACUCARE F1-0 FFM LGE-ROW 5PK	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 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
61032 Pixi Pediatric Mask-EUR3 61031 Pixi Pediatric Mask-EUR1, EUR2	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
62100 Mirage FX Mask Sys-EUR1 62101 Mirage FX Mask Sys-EUR2 62102 Mirage FX Mask Sys-EUR3 62115 Mirage FX Mask Sys WD-EUR1 62116 Mirage FX Mask Sys WD-EUR2 62117 Mirage FX Mask Sys WD-EUR3 62132 Mirage FX for Her Mask Sys - EUR1 62133 Mirage FX for Her Mask Sys - EUR2 62139 Mirage FX for Her Mask Sys–EUR3	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
62782 NV Quattro Air FFM XSML - EUR 62783 NV Quattro Air FFM SML - EUR 62784 NV Quattro Air FFM MED - EUR 62785 NV Quattro Air FFM LGE - EUR	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
64020 AirFit F20 NV SML Sys ROW 64021 AirFit F20 NV MED Sys ROW 64022 AirFit F20 NV LGE Sys ROW 63447 AIRFIT F20 LGE SYS - SLM 63446 AIRFIT F20 MED SYS - SLM 63445 AIRFIT F20 SML SYS - SLM	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
64114 AirFit F30 SML Sys MultiHole- EU 64110 AirFit F30 SML Sys - EU 64115 AirFit F30 MED Sys MultiHole- EU 64111 AirFit F30 MED Sys – EU 64105 AIRFIT F30 MED SYS - SLM 64104 AIRFIT F30 SML SYS - SLM	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
60762 NV AcuCare F1-1 FFM SML-EU1 20pk 60763 NV AcuCare F1-1 FFM MED-EU1 20pk 60764 NV AcuCare F1-1 FFM LGE-EU1 20pk 60789 NV AcuCare F1-1 FFM SML-EU1 5pk 60790 NV AcuCare F1-1 FFM MED-EU1 5pk 60791 NV AcuCare F1-1 FFM LGE-EU1 5pk 60974 NV ACUCARE F1-1 FFM SML-ROW 60975 NV ACUCARE F1-1 FFM MED-ROW 60976 NV ACUCARE F1-1 FFM LGE-ROW 60993 NV ACUCARE F1-1 FFM SML ROW 5PK 60994 NV ACUCARE F1-1 FFM MED ROW 5PK 60995 NV ACUCARE F1-1 FFM LGE ROW 5PK	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
60765 AcuCare F1-4 FFM SML-EU1 20pk 60766 AcuCare F1-4 FFM MED-EU1 20pk 60767 AcuCare F1-4 FFM LGE-EU1 20pk	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 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
60792 AcuCare F1-4 FFM SML-EU1 5pk 60793 AcuCare F1-4 FFM MED-EU1 5pk 60794 AcuCare F1-4 FFM LGE-EU1 5pk 60977 ACUCARE F1-4 FFM SML-ROW 60978 ACUCARE F1-4 FFM MED-ROW 60979 ACUCARE F1-4 FFM LGE-ROW 60996 ACUCARE F1-4 FFM SML-ROW 5PK 60997 ACUCARE F1-4 FFM MED-ROW 5PK 60998 ACUCARE F1-4 FFM LGE ROW 5PK			
62704 Quattro Air FFM XSML-EUR1 62705 Quattro Air FFM SML-EUR1 62706 Quattro Air FFM MED-EUR1 62707 Quattro Air FFM LGE-EUR1 62709 Quattro Air FFM SML-EUR2 62710 Quattro Air FFM MED-EUR2 62711 Quattro Air FFM LGE-EUR2 62713 Quattro Air FFM SML-EUR3 62714 Quattro Air FFM MED-EUR3 62715 Quattro Air FFM LGE-EUR3 62743 Quattro Air FFM for Her XSML-EUR1 62744 Quattro Air FFM for Her SML-EUR1 62745 Quattro Air FFM for Her MED-EUR1 62746 Quattro Air FFM for Her XSML-EUR2 62747 Quattro Air FFM for Her SML-EUR2 62748 Quattro Air FFM for Her MED-EUR2 62749 Quattro Air FFM for Her XSML-EUR3 62750 Quattro Air FFM for Her SML-EUR3 62751 Quattro Air FFM for Her MED-EUR3	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
64001 NV ELBOW F20 ACCESSORY	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
38808 HUMIDX 50PK 38809 HumidX 3PK 38810 HumidX 6PK 38846 HumidX 38811 HumidX Plus 50PK 38812 HumidX Plus 3PK 38813 HumidX Plus 6PK 38847 HumidX Plus 38015 HUMIDX F20 38012 HUMIDX F20 3PK 38013 HUMIDX F20 6PK	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
36858 S9/AIR10 FILTER, HYPO, 50 PACK 36856 S9/AIR10 FILTER, HYPO, 2 PACK 36857 S9/AIR10 FILTER, HYPO, 12 PACK 36855 S9/AIR10 FILTER, HYPO, 1 PACK	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 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
38857 AirMini Filter Hypo 2PK 38858 AirMini Filter Hypo 12PK			
27902 Remote Alarm II, ROW	☒ Class IIb / Class *IIb implantable (exempted)*	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
24988 RESMED LEAK VALVE - ROW (DISP)	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
38823 N20 AIRMINI SETUP PACK 38825 F20 AIRMINI SETUP PACK 38010 F30 Airmini setup pack 38011 F20 AirMini Setup Pack + Humidx	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
38824 P10 AirMini Mask Pack	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
37357 ClimateLineAir Oxy *37296 ClimateLine Air*	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
28403 Lumis HFT EUR2 28401 Lumis HFT EUR1	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
63516 AirFit N20 SML (for Her) - EU3 63513 AirFit N20 SML (for Her) - EU2 63510 AirFit N20 SML (for Her) - EU1 63509 AirFit N20 SML - EU1 63517 AirFit N20 MED Sys - EU3 63514 AirFit N20 MED Sys - EU2 63511 AirFit N20 MED Sys - EU1 63518 AirFit N20 LGE Sys - EU3 *63515 AirFit N20 LGE Sys - EU2* 63512 AirFit N20 LGE Sys - EU1 63507 AIRFIT N20 LGE SYS - SLM 63506 AIRFIT N20 MED SYS - SLM 63505 AIRFIT N20 SML (FOR HER) - SLM 63504 AIRFIT N20 SML SYS - SLM	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
63716 AirFit N20 CL SML Sys - EU3 63713 AirFit N20 CL SML Sys - EU2 63710 AirFit N20 CL SML Sys - EU1 63717 AirFit N20 CL MED Sys - EU3 63714 AirFit N20 CL MED Sys - EU2 63711 AirFit N20 CL MED Sys - EU1 63718 AirFit N20 CL LGE Sys - EU3 *63715 AirFit N20 CL LGE Sys - EU2* 63712 AirFit N20 CL LGE Sys - EU1	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
63910 AIRTOUCH N20 SML (FOR HER) - EU1	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01;

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
63909 AIRTOUCH N20 SML - EU1 63911 AIRTOUCH N20 MED SYS - EU1 63912 AIRTOUCH N20 LGE SYS - EU1			NB# 0123
22243 AirMini by ResMed iOS App 22244 AirMini by ResMed Android App	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
14922 AIR TUBING - Grey 3 Metre 14980 AIR TUBING - GREY 3 METRE 14994 Tubing, Clear-Gray Ribbed 6(1.83m) 36810 SLIMLINE TUBING 37394 Air10 Tubing Elbow 14948 GREY TUBING - CUFFED,STD TUBING 2M	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
61204 Mirage Quattro FFM XSML - EUR1 61205 Mirage Quattro FFM SML - EUR1 61206 Mirage Quattro FFM MED - EUR1 61207 Mirage Quattro FFM LGE - EUR1 61208 Mirage Quattro FFM XSML - EUR2 61209 Mirage Quattro FFM SML - EUR2 61210 Mirage Quattro FFM MED - EUR2 61211 Mirage Quattro FFM LGE - EUR2 61220 MIRAGE QUATTRO FFM XSML-FRA 61221 MIRAGE QUATTRO FFM SML-FRA 61222 MIRAGE QUATTRO FFM MED-FRA 61223 MIRAGE QUATTRO FFM LGE-FRA 61228 Mirage Quattro FFM XSML - EUR3 61229 Mirage Quattro FFM SML - EUR3 61230 Mirage Quattro FFM MED - EUR3 61231 Mirage Quattro FFM LGE - EUR3	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
61105 HOSPITAL NASAL MASK SYST LGE-ROW 61104 HOSPITAL NASAL MASK SYST MED-ROW	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
36996 ClimateLine Max Oxy 36997 CLIMATELINE MAX TUBING 36995 ClimateLine Tubing	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
24928 H4i for Stellar GERMANY 24929 H4i for Stellar EUR GP 1, UK 24930 H4i for Stellar EUR GP 2 24936 H4i for Stellar FRANCE	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
63822 SLM AIRFIT N30I SML STPK 63821 SLM AIRFIT N30I STD STPK 63871 SLM AIRFIT P30I STD STPK	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
60646 NV UMFFM SYS LGE SHW-EUR1 60647 NV UMFFM SYS LGE STD-EUR1 60652 NV UMFFM SYS LGE STD-EUR2	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123

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60644 NV UMFFM SYS MED SHW-EUR1 60645 NV UMFFM SYS MED STD-EUR1 60650 NV UMFFM SYS MED STD-EUR2 60642 NV UMFFM SYS SML SHW-EUR1 60643 NV UMFFM SYS SML STD-EUR1 60648 NV UMFFM SYS SML STD-EUR2 60153 Mirage Activa LT Mask LG-WD-EUR1 60151 Mirage Activa LT Mask MED - EUR1	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
62927 AirFit P10 for Her SYS - SLM 62925 AirFit P10 Mask SYSTEM - SLM	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
26960 ResMed Oxygen Connector Port	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123
37299 HumidAir Standard Tub	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 049861 0158 Rev. 01; NB# 0123

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-04-25	73580288; 713210119; 713259724; 713260923; 713295236; 713316588	Initial issue