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

Ningbo Luke Medical Devices Co., Ltd.
Gujiayan, Yangming Road
315400 YUYAO CITY, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
86250	713336600	medical_devices@tuvsud.com	N/A	2024-05-07	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 086250 0025 Rev. 00

Reference: 713336600

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: CN-MF-000011732

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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 086250 0025 Rev. 00

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

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

6th May 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

Xujian Liu
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
Drainage Bag (Basic UDI-DI: 697024089DBWW)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 086250 0019 Rev. 01 (or GCQ 086250 0024 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Nasopharyngeal Airway (Basic UDI-DI: 697024089NAXS)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 086250 0019 Rev. 01 (or GCQ 086250 0024 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Oropharyngeal Airway (Basic UDI-DI: 697024089OASQP)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 086250 0019 Rev. 01 (or GCQ 086250 0024 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Suction Reservoir (Basic UDI-DI: 697024089SRZB)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate # G2S 086250 0019 Rev. 01 (or GCQ 086250 0024 Rev. 00); NB# 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number:	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Vessel loop (Basic UDI-DI: 697024089VLZ8)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A Only Device Name Change MDD Device Name: **'Silicon Loops'** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 086250 0019 Rev. 01 (or GCQ 086250 0024 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Anesthesia Mask (Basic UDI-DI: 697024089AMPPF 697024089AMPSK2 697024089AMSPM 697024089AMSSKB)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Breathing Circuit (Basic UDI-DI: 697024089BCWS)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Breathing Filter (Basic UDI-DI: 697024089BFWY)	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A or	☒ Certification as follows:

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 IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Catheter Mount (Basic UDI-DI: 697024089CMXH)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Drainage Tube (Basic UDI-DI: 697024089DTY2)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Endotracheal Tube (Basic UDI-DI: 697024089ETY5)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had

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 III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Heat and Moisture Exchanger (Basic UDI-DI: 697024089HMEPU)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Laryngeal Mask Airway (Basic UDI-DI: 697024089LMAQ8 697024089LMAPKU)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Manual Resuscitator (Basic UDI-DI: 697024089PMRRW 697024089MRYR)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Oxygen Mask (Basic UDI-DI: 697024089OMYM)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A or	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); 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 IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Stomach Tube (Basic UDI-DI: 697024089STZF)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Tracheostomy Tube (Basic UDI-DI: 697024089TTZJ)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Wound Drainage System (Basic UDI-DI: 697024089WDSS8)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2 086250 0018 Rev.01 (or GCQ 086250 0021 Rev. 00); NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

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	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-06	713336600	Initial issue

Ningbo Luke Medical Devices Co., Ltd.
Add: Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, People's Republic of China.
Web: www.canack.com Tel: +86-574-22661850 Mail: info@canack.com

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	**Ningbo LUKE MEDICAL DEVICES Co., Ltd**
Manufacturer address and contact details	Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, CHINA
Single Registration Number (SRN) (if available)	Manufacturer CN-MF000011732

Authorised Representative name (if applicable)	**Shanghai International Holding Corp.GmbH(Europe)**
Authorised Representative address and contact details	Eiffestrasse 80, 20537 Hamburg, Germany TEL:+49-40-2513175
Single Registration Number (SRN) (if available)	Manufacturer DE-AR-000000001

Notified body name (if applicable)	**TUV** □ **See attached schedule**
Notified body number (if applicable)	0123 □ See attached schedule

[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.

Directive Certificate number(s) to which this confirmation is made (if applicable)	GCQ 086250 0021 Rev. 00 GCQ 086250 0024 Rev. 00 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024.5.26 □ See attached schedule
End date of extended validity/transition period	□ See attached schedule

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

[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

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.

☐ 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.

Signed for and on behalf of the manufacturer:

Full Company Name : Ningbo Luke Medical devices co.,Ltd

Location & Date :Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, CHINA

2023-10-24

Signature Sijia xu

Print Name, Title : Sijia Xu / Quality Manager

Contact Details (at least email) : xusijia@med-luke.com

Schedule of Devices

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

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
SDS200B+DB1000 (SDS200) Wound drainage system (bag + reservoir)	GCQ 086250 0021 Rev. 00	26/05/2024	TUV Sud (0123)	TUV Sud (0123)	26/09/2024	Not applicable
DB1000 Drainage bag	GCQ 086250 0024 Rev. 00	26/05/2024	TUV Sud (0123)	TUV Sud (0123)	26/09/2024	Not applicable

[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)

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

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 086250 0024 Rev. 00

Manufacturer:

Ningbo Luke Medical Devices Co., Ltd.
Gujiayan, Yangming Road
315400 Yuyao City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD): **G2S 086250 0019 Rev. 01**

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ 086250 0024 Rev. 00

Report No.: SH2265101

Valid until: 2024-05-26

Issue Date: 2023-05-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 086250 0024 Rev. 00

Product Category(ies): **Oropharyngeal Airways,**
Suction Reservoirs,
Drainage Bags,
Nasopharyngeal Airways,
Catheter Fixation Devices,
Spacer for Aerosols, Silicone Loops.

Description of Change:

Reduction of product category(ies): Sterile Surgical Packs.

Reduction of facility: CANACK TECHNOLOGY LTD. Room 1308-2, Building A, Huaxing Times Square, No. 478 Wensan Road, Xihu District 310007 Hangzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

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