DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 066149 0020 Rev. 05

Holder of Certificate: **HANGZHOU FUSHAN MEDICAL APPLIANCES CO., LTD.**
No. 1288 South Jinxi Road
Linglong Industrial Park
Lin'an District
311301 Hangzhou City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate:

Design and Development, Production and Distribution of PEG Kit, Drainage Kit, Disposable Central Venous Catheter and Kits, Mini-button Gastrostomy Tube Kit, Double Lumen Endobronchial Tube, Disposable Hemodialysis Catheter Kit, Gastrostomy Tube, Huber Needle, Stoma Measuring Tube, Gastric Balloon, Cervical Ripening Balloon, Gastric Jejunal Feeding Tube, Silicone Tube, Double J Ureteral Stent, Dilation Sheath.
Production and Distribution of Silicone Urethral Catheter, Silicone Reservoir, Laryngeal Mask Airway, Lacrimal Dilation Tube, Miniature Infusion Pump, Oxygen Tube, Silicone Urinary Catheter, Rectal Tube, Stomach Tube, Nasogastric Tube, Trocar, Tracheal Tube, Drainage Tube, Nebulizer, Supra Laryngeal Airway, Mask, Urine Bag, Suction Tube Kit, Yankauer Handle, Resuscitator, Guedel/Oropharyngeal Airway, Intravenous Catheter, Infusion Access Adapter, Enteral Feeding Bag, Breathing Trainer, Stoma Stoppers, Pharachute Supralaryngeal Airway (PSA), Pessary, Colostrum Collection Kit, Stapler-Bioabsorbable Skin Closure System, Catheter Dressing, Silicone Foley Catheter Kit, Penrose Tube, Catheter Cap, Nasal Pharyngeal Airway, Silicone Seal, Fluid Management Pack, Latex Foley Catheter, Vaginal Speculum, Laryngoscope, Retractor, Anal Speculum, Rigid Suction Cannula.

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 066149 0020 Rev. 05

Report No.: SH2451201
Valid from: 2025-01-13
Valid until: 2026-07-03

Date, 2025-01-13

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Iurcu Nicolae
Date: 2025.06.02 07:16:27 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 066149 0020 Rev. 05

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

HANGZHOU FUSHAN MEDICAL APPLIANCES CO., LTD.
No. 1288 South Jinxi Road, Linglong Industrial Park, Lin'an District, 311301 Hangzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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HANGZHOU FUSHAN MEDICAL
APPLIANCES CO., LTD.
Linglong Industrial Park
No. 1288 South Jinxi Road
Lin'an District
311301 HANGZHOU CITY, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
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SÜD Product Service GmbH
Confirmation Letter
CL 066149 0022 Rev. 00

Reference: SH2351200_CL

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-000022768

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.

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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 (3a) 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)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2023-08-02

TÜV SÜD Product Service GmbH
Medical and Health Services

Ms. Yi Wu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Claus Matthias Mumme
Application Reviewer

Product Service

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
Device 1 Gastrostomy Tube and Accessories：PEG Kit & Gastrostomy Kit (Basic UDI -DI: 69536763GTA001R4)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 066149 0021 Rev.01; NB# 0123 Certificate # G2 066149 0017 Rev.01; NB # 0123
Device 2 Laryngeal Mask Airway (Basic UDI -DI: 69536763LMA002QS)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G2 066149 0017 Rev.01; NB# 0123
Device 3 Stomach Tube (Basic UDI -DI: 69536763NA002P8)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G2 066149 0017 Rev.01; NB# 0123
Device 4 Drainage Tube and Accessories (Basic UDI -DI: 69536763DTA001PV)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G2 066149 0017 Rev.01; NB# 0123
Device 5 Silicone Reservoir (Basic UDI -DI: 69536763SR001UL)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 066149 0019 Rev.01; NB# 0123

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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 with measuring function ☐ Class III implantable custom-made-device		

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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:

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 Revision History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2023-08-02	SH2351200_CL	Initial issue