

TÜV Rheinland LGA Products GmbH • 51105 Köln

Changzhou Health Microport Medical Device Co., Ltd.
No. 11 Tuanjie Road, Tianning District,
Changzhou, 213018 Jiangsu,
P.R. China

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Date May 21, 2024

Notified Body Confirmation Letter

Reference. : Chang_PLA0_2024-05-14; order #326024416

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has 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 following manufacturer:

Changzhou Health Microport Medical Device Co., Ltd.
No. 11 Tuanjie Road, Tianning District,
Changzhou, 213018 Jiangsu,
P.R. China
SRN Number (if available): CN-MF-000033536

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 the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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, by March 20, 2023 for the relevant devices.

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Dr.-Ing. Michael Fübi

The transition timelines 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 (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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)

On behalf of the Notified Body



FuXiu Sheng
Certification body

Table 1: Devices covered by this letter and for which the NB 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 at the pre-application stage) | 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 |
|---|---|--|--|
| Hemorrhoidal Multi-Band Ligator with Anoscope Basic UDI-DI: 69518622HM/601GK | Class IIa | NA | Certificate: HD 60147762 0001 #0197 |
| Ligatures Endoscopic Loops Basic UDI-DI: 69518622HM/105G2 | Class IIa | NA | Certificate: HD 60147762 0001 #0197 |
| Disposable Injection Needles Basic UDI-DI: 69518622HM/106G4 | Class IIa | NA | Certificate: HD 60147762 0001 #0197 |
| Disposable Balloon Dilatation Catheters Basic UDI-DI: 69518622HM/301G4 | Class IIa | NA | Certificate: HD 60147762 0001 #0197 |
| Disposable Biopsy Forceps Basic UDI-DI: 69518622HM/101FS | Class IIa | NA | Certificate: HD 60147762 0001 #0197 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | 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 |
|---|--|---|---|
| Disposable Cytology Brushes Basic UDI-DI: 69518622HM/102FU | Class IIa | NA | Certificate: HD 60147762 0001 #0197 |
| Disposable Grasping Forceps Basic UDI-DI: 69518622HM/108G8 | Class IIa | NA | Certificate: HD 60147762 0001 #0197 |
| Bougie Dilator Sets Basic UDI-DI: 69518622HM/302G6 | Class IIa | NA | Certificate: HD 60147762 0001 #0197 |
| Guide Wires Basic UDI-DI: 69518622HM/109GA | Class IIa | NA | Certificate: HD 60147762 0001 #0197 |
| Disposable Polyp Snares Basic UDI-DI: 69518622HM/701GQ | Class IIb excluding Class IIb implantable non-WET | NA | Certificate: HD 60147762 0001 #0197 |
| Multi-chamber Polyp Traps Basic UDI-DI: 69518622HM/802GX | Class I devices placed on the market in sterile condition | NA | Certificate: HD 60147762 0001 #0197 |
| Biopsy Valves Basic UDI-DI: 69518622HM/801GV | Class I devices placed on the market in sterile condition | NA | Certificate: HD 60147762 0001 #0197 |
| Non-vascular Ni-Ti Alloy Self-expanding Stent System Polymer-metal Oesophageal Stent Basic UDI-DI: 69518622HM/401POSRD | Class IIb implantable non-WET device | NA | Certificate: HD 60147762 0001 #0197 |
| Non-vascular Ni-Ti Alloy Self-expanding Stent System Bare-metal Oesophageal Stent Basic UDI-DI: 69518622HM/401BOSP7 | Class IIb implantable non-WET device | NA | Certificate: HD 60147762 0001 #0197 |
| Non-vascular Ni-Ti Alloy Self-expanding Stent System Polymer-metal Biliary Stent Basic UDI-DI: 69518622HM/401PBSQ6 | Class IIb implantable non-WET device | NA | Certificate: HD 60147762 0001 #0197 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | 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 |
|--|--|---|---|
| Non-vascular Ni-Ti Alloy Self-expanding Stent System Bare-metal Biliary Stent Basic UDI-DI: 69518622HM/401BBSMY | Class IIb implantable non-WET device | NA | Certificate: HD 60147762 0001 #0197 |
| Non-vascular Ni-Ti Alloy Self-expanding Stent System Polymer-metal Colonic Stent Basic UDI-DI: 69518622HM/401PCSQ9 | Class IIb implantable non-WET device | Certificate: HD 60147762 0001 #0197 | NA |
| Non-vascular Ni-Ti Alloy Self-expanding Stent System Bare-metal Colonic Stent Basic UDI-DI: 69518622HM/401BCSN3 | Class IIb implantable non-WET device | Certificate: HD 60147762 0001 #0197 | NA |
| Non-vascular Ni-Ti Alloy Self-expanding Stent System Polymer-metal Tracheal Stent Basic UDI-DI: 69518622HM/401PTSRU | Class IIb implantable non-WET device | Certificate: HD 60147762 0001 #0197 | NA |
| Non-vascular Ni-Ti Alloy Self-expanding Stent System Bare-metal Tracheal Stent Basic UDI-DI: 69518622HM/401BTSPN | Class IIb implantable non-WET device | Certificate: HD 60147762 0001 #0197 | NA |
| Disposable Endoscopic Linear Cutter Staplers Basic UDI-DI: 69518622QQW-SXW | Class IIa | Certificate: HD 60147762 0001 #0197 | NA |
| Disposable Reloads of Endoscopic Linear Cutter Staplers Basic UDI-DI: 69518622QQW7N | Class IIb excluding Class IIb implantable non-WET | Certificate: HD 60147762 0001 #0197 | NA |
| Disposable Circular Staplers Basic UDI-DI: 69518622GWH5Q | Class IIb excluding Class IIb implantable non-WET | Certificate: HD 60147762 0001 #0197 | NA |
| Disposable Circular Staplers for Haemorrhoids Basic UDI-DI: 69518622GGW-TSC | Class IIb excluding Class IIb implantable non-WET | NA | Certificate: HD 60147762 0001 #0197 |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | 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 |
|--|---|--|--|
| Disposable Linear Staplers Basic UDI-DI: 69518622ZWH8P | Class IIb excluding Class IIb implantable non-WET | NA | Certificate: HD 60147762 0001 #0197 |
| Disposable Linear Cutter Staplers Basic UDI-DI: 69518622ZQW93 | Class IIb excluding Class IIb implantable non-WET | NA | Certificate: HD 60147762 0001 #0197 |
| Disposable Curved Cutter Staplers Basic UDI-DI: 69518622Hqw69 | Class IIb excluding Class IIb implantable non-WET | NA | Certificate: HD 60147762 0001 #0197 |
| Disposable Skin Staplers Basic UDI-DI: 69518622PWH75 | Class IIa | NA | Certificate: HD 60147762 0001 #0197 |

Table 2: Devices covered by this letter and for which the NB 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 at the pre-application stage) | 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 |
|---|---|--|--|
| None | | | |

Confirmation Letter Revision History

| Date | NB internal reference traceable to each version of the letter | Action |
|------------|---|---------------|
| 2024-05-21 | Chang_CL607_2024-05-21 | Initial issue |
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