

TÜV Rheinland LGA Products GmbH • 51105 Köln

Hangzhou Minsheng Lide Medical Science & Technology Co., Ltd.
101C No.22 Xinyan Road, Yuhang Economic and Technological Development
Area, Yuhang District, Hangzhou,
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Contact

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Date May 28, 2024

Notified Body Confirmation Letter

Reference. : HANGZ_PLA0_2024-05-24; order #326014892

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:

Hangzhou Minsheng Lide Medical Science & Technology Co., Ltd.
101C No.22 Xinyan Road, Yuhang Economic and Technological Development Area,
Yuhang District, Hangzhou,
311100 Zhejiang,
P.R. China
SRN Number (if available): CN-MF-000041997

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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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Chairman of the
Supervisory Board

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
Bone Level Implant Basic UDI-DI: 69419264LD001KX	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Implant)	Certificate # HD 60128156 0001 NB# 0197
Bone Level Implant Cover Screw Basic UDI-DI: 69419264LD002KZ	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Cover Screw)	Certificate # HD 60128156 0001 NB# 0197
Bone Level Implant Healing Abutment Basic UDI-DI: 69419264LD003L3	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Healing Abutment)	Certificate # HD 60128156 0001 NB# 0197
Bone Level Implant Solid Abutment Basic UDI-DI: 69419264LD004L5	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Solid Abutment)	Certificate # HD 60128156 0001 NB# 0197
Bone Level Implant Cement Abutment Basic UDI-DI: 69419264LD005L7	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Cement Abutment)	Certificate # HD 60128156 0001 NB# 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
Bone Level Implant Angled Abutment Basic UDI-DI: 69419264LD006L9	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Angled Abutment)	Certificate # HD 60128156 0001 NB# 0197
Bone Level Implant Milling Abutment Basic UDI-DI: 69419264LD007LB	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Milling Abutment)	Certificate # HD 60128156 0001 NB# 0197
Bone Level Implant Temporary Abutment Basic UDI-DI: 69419264LD008LD	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Temporary Abutment)	Certificate # HD 60128156 0001 NB# 0197
Bone Level Implant Retention Abutment Basic UDI-DI: 69419264LD009LF	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Retention Abutment)	Certificate # HD 60128156 0001 NB# 0197
Bone Level Implant Link Abutment Basic UDI-DI: 69419264LD010KY	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Link Abutment)	Certificate # HD 60128156 0001 NB# 0197
Bone Level Implant Profile Abutment Basic UDI-DI: 69419264LD011L2	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Profile Abutment)	Certificate # HD 60128156 0001 NB# 0197
Bone Level Implant Abutment Screw Basic UDI-DI: 69419264LD012L4	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Bone Level Abutment Screw)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Basic UDI-DI: 69419264LD013L6	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Implant)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Cover Screw Basic UDI-DI: 69419264LD014L8	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Cover Screw)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Closure Screw Basic UDI-DI: 69419264LD015LA	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Closure Screw)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Healing Abutment Basic UDI-DI: 69419264LD016LC	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Healing Abutment)	Certificate # HD 60128156 0001 NB# 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
Tissue Level Implant Solid Abutment Basic UDI-DI: 69419264LD017LE	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Solid Abutment)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Excellent Solid Abutment Basic UDI-DI: 69419264LD018LG	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Excellent Solid Abutment)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Cement Abutment Basic UDI-DI: 69419264LD019LJ	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Cement Abutment)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Angled Abutment Basic UDI-DI: 69419264LD020L3	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Angled Abutment)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Milling Abutment Basic UDI-DI: 69419264LD021L5	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Milling Abutment)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Temporary Abutment Basic UDI-DI: 69419264LD022L7	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Temporary Abutment)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Retention Abutment Basic UDI-DI: 69419264LD023L9	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Retention Abutment)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Link Abutment Basic UDI-DI: 69419264LD024LB	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Link Abutment)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Profile Abutment Basic UDI-DI: 69419264LD025LD	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Profile Abutment)	Certificate # HD 60128156 0001 NB# 0197
Tissue Level Implant Abutment Screw Basic UDI-DI: 69419264LD026LF	Class IIb excluding Class IIb implantable non-WET	Dental Implants and Attachments (Tissue Level Abutment Screw)	Certificate # HD 60128156 0001 NB# 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
2024-05-28	HANGZ_CL607_2024-05-28	Initial issue