

TÜV Rheinland LGA Products GmbH • 51105 Köln

Wujiang City Shenlong Medical Health Product Co., Ltd.
Gangzi Cun, Shenta, Lili Town, Wujiang District, Suzhou,
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P.R. China

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Date March 04, 2024

Notified Body Confirmation Letter

Reference. : 244590405

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:

Wujiang City Shenlong Medical Health Product Co., Ltd.
Gangzi Cun, Shenta, Lili Town, Wujiang District, Suzhou,
215213 Jiangsu,
P.R. China
SRN Number: CN-MF-000017191

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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

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



Herbert Zhong
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
Disposable Acupuncture Needles Model: SL101 Basic UDI-DI code 69368995SL101Z9	Class IIa	Disposable Acupuncture Needles Model Needle diameter 0.16mm-0.45mm, length 13-150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL102 Basic UDI-DI code 69368995SL102ZB	Class IIa	Disposable Acupuncture Needles Model Needle diameter 0.16mm-0.45mm, length 13-150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL103 Basic UDI-DI code 69368995SL103ZD	Class IIa	Disposable Acupuncture Needles Model Needle - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL104	Class IIa	Disposable Acupuncture Needles Model Needle diameter 0.16mm-	DD 60136869 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
Basic UDI-DI code 69368995SL104ZF		0.45mm, length 13-150mm.	
Disposable Acupuncture Needles Model: SL105 Basic UDI-DI code 69368995SL105ZH	Class IIa	Disposable Acupuncture Needles Model Needle diameter - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL106 Basic UDI-DI code 69368995SL106ZK	Class IIa	Disposable Acupuncture Needles Model Needle - 13- 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL107 Basic UDI-DI code 69368995SL107ZM	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL108 Basic UDI-DI code 69368995SL108ZP	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL109 Basic UDI-DI code 69368995SL109ZR	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL110 Basic UDI-DI code 69368995SL110ZA	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL111 Basic UDI-DI code 69368995SL111ZC	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL112 Basic UDI-DI code 69368995SL112ZE	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 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 Acupuncture Needles Model: SL113 Basic UDI-DI code 69368995SL113ZG	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL114 Basic UDI-DI code 69368995SL114ZJ	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL115 Basic UDI-DI code 69368995SL115ZL	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL116 Basic UDI-DI code 69368995SL116ZN	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL117 Basic UDI-DI code 69368995SL117ZQ	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL118 Basic UDI-DI code 69368995SL118ZS	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL119 Basic UDI-DI code 69368995SL119ZU	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL120 Basic UDI-DI code 69368995SL120ZD	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles	Class IIa	Disposable Acupuncture Needles Model Needle	DD 60136869 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
Model: SL121 Basic UDI-DI code 69368995SL121ZF		- - 150mm.	
Disposable Acupuncture Needles Model: SL122 Basic UDI-DI code 69368995SL122ZH	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL123 Basic UDI-DI code 69368995SL123ZK	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL124 Basic UDI-DI code 69368995SL124ZM	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL125 Basic UDI-DI code 69368995SL125ZP	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL126 Basic UDI-DI code 69368995SL126ZR	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL127 Basic UDI-DI code 69368995SL127ZT	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Acupuncture Needles Model: SL128 Basic UDI-DI code 69368995SL128ZV	Class IIa	Disposable Acupuncture Needles Model Needle - - 150mm.	DD 60136869 0001 #0197
Disposable Press needles Model: SL129 Basic UDI-DI code 69368995SL129Z2	Class IIa	Disposable Press needles Model diameter: - 75mm length 1.3mm-2.00mm.	DD 60136869 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
		Helical diameter 2.6-3.2mm	
Disposable Press needles Model: SL130 Basic UDI-DI code 69368995SL130ZG	Class IIa	Disposable Press needles Model diameter: - 75mm length 1.3mm-2.00mm. Helical diameter 2.6-3.2mm	DD 60136869 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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/04	244590405	Initial issue