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

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PEOPLE'S REPUBLIC OF CHINA

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TÜV SÜD Product Service GmbH
Confirmation Letter
CL 120215 0003 Rev. 00

Reference: SH24436A03

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-000012826

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(MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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=cert:CL 120215 0003 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-06-20

TÜV SÜD Product Service GmbH
Medical and Health Services

Jia Zhu

Ms. Jia ZHU
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Clara Höhneke
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**
Device 1 **Sterile Gauze Balls With X-ray Detectable Thread (Basic UDI -DI: 6947329669473296093063P)**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 059454 0028 Rev. 01; NB# 0123
Device 2 **Sterile Gauze Swabs with X-ray Detectable Thread (Basic UDI -DI: 6947329669473296092834 4)**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 059454 0028 Rev. 01; NB# 0123
Device 3 **Sterile Disposable Dressing Packs and Procedure Packs (Basic UDI -DI: 6947329669473296093133L 6947329669473296089274N 6947329669473296089344K 6947329669473296089414G 6947329669473296089584Z 6947329669473296089654W 6947329669473296089724T 6947329669473296089895C 6947329669473296082073D)**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 059454 0028 Rev. 01; NB# 0123
Device 4 **Sterile Dissecting & Tissue Forceps (Basic UDI -DI: 6947329669473296026352U)**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 059454 0028 Rev. 01; NB# 0123
Device 5 **Sterile Haemostatic Forceps (Basic UDI -DI: 6947329669473296026422R)**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 059454 0028 Rev. 01; NB# 0123
Device 6	☒ Class IIa	☒ N/A	☒ 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
Sterile Retractors (Basic UDI -DI: 6947329669473296026663 7)			Certificate # G2 059454 0028 Rev. 01; NB# 0123
Device 7 **Sterile Curets (Basic UDI -DI: 6947329669473296026733 4)**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 059454 0028 Rev. 01; NB# 0123
Device 8 **Sterile Scissors (Basic UDI -DI: 6947329669473296026282X)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 059454 0028 Rev. 01; NB# 0123
Device 9 **Sterile Needle Holders (Basic UDI -DI: 6947329669473296024372N)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 059454 0028 Rev. 01; NB# 0123
Device 10 **Sterile Disposable Dressing Packs and Procedure Packs (Basic UDI -DI: 6947329669473296024372N 6947329669473296087674Q 6947329669473296087744M 6947329669473296091603K 6947329669473296091083H 6947329669473296091153E 6947329669473296091223B 6947329669473296091393U 6947329669473296091463R 6947329669473296091533N)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 11 **Sterile Drape / Surgical Drapes (Basic UDI -DI: 6947329669473296024442K)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 12	☒ Class I devices in sterile condition	☒ N/A	☒ 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
Sterile Surgical Packs / Kit (Basic UDI -DI: 6947329669473296024512G 6947329669473296091744)			Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 13 **Sterile Baby Delivery Kit (Basic UDI -DI: 6947329669473296025362R 6947329669473296091843Z)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 14 **Sterile Catheterization Pack/Catheter Pack (Basic UDI -DI: 6947329669473296025432N 6947329669473296091913W)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 15 **Sterile Suture Removal Kit (Basic UDI -DI: 6947329669473296025673 4 6947329669473296090233 8)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 16 **Sterile Surgical Gown (Basic UDI -DI: 6947329669473296024752W)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 17 **Sterile Non-woven Swabs (Basic UDI -DI: 6947329669473296024132 8)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 18 **Sterile Gauze Swabs (Basic UDI -DI: 6947329669473296023832Q)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 19 **Sterile Gauze Balls**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; 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**
(Basic UDI -DI: 6947329669473296092903Z)			
Device 20 **Sterile Tongue Depressors (Basic UDI -DI: 6947329669473296023902M)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 21 **Sterile Medical Applicators (Basic UDI -DI: 6947329669473296024 2025)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 22 **Sterile Medical Bandage (Basic UDI -DI: 6947329669473296093203H)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 23 **Sterile Medical Gloves (Basic UDI -DI: 6947329669473296024062B)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 24 **Sterile Disposable Medical Basin (Basic UDI -DI: 6947329669473296024993C)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 25 **Sterile Dialysis Kit/Haemodialysis Fistula ON/OFF Kit** (**Basic UDI -DI: 6947329669473296025292U 6947329669473296090093E 6947329669473296094744D 6947329669473296094814A)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 26	☒ Class I devices in sterile condition	☒ N/A	☒ 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**
Sterile Male Circumcision Kit (Basic UDI -DI: 6947329669473296025502K 6947329669473296090163B)			Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 27 **Sterile Suture Kit (Basic UDI -DI: 6947329669473296092453U)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 28 **Sterile Tracheostomy Pack (Basic UDI -DI: 6947329669473296025812W 6947329669473296092523R)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 29 **Sterile Umbilical Catheter Tray Kit (Basic UDI -DI: 6947329669473296025983F 6947329669473296090473N)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 30 Sterile Chest Tube Tray Kit (Basic UDI -DI: 6947329669473296026042H 6947329669473296090543K**)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 31 Sterile PICC Catheter Insertion Dressing Care Kit (Basic UDI -DI: 6947329669473296026112E	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; 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**
6947329669473296090613G**)**			
Device 32 Sterile First Aid Kit (Basic UDI -DI: 6947329669473296024822T 6947329669473296090783Z**)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 33 Sterile Disposable Medical Bedsheets (Basic UDI -DI: 6947329669473296024682Z**)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 34 Sterile Disposable Medical Tray (Basic UDI -DI: 6947329669473296025052E**)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 35 Sterile Disposable Medical Forceps (Basic UDI -DI: 6947329669473296025122B**)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 36 Sterile Foam Swabstick (Basic UDI -DI: 6947329669473296026973J**)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123
Device 37 Sterile Adhesive Fixation Clip (Basic UDI -DI: 6947329669473296027032L**)**	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 059454 0026 Rev. 01; NB# 0123

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 Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-06-20	**SH2443600_CL**	Initial issue