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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
002037	713265109 713311920	+86 21 6142 4449 Yu.Qiu@tuvsud.com		2023-12-11	1 of 15

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 002037 0021 Rev. 00

Reference: 713265109 | 713311920

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-000007970

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(MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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)

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.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 002037 0021 Rev. 00

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2023-12-11

TÜV SÜD Product Service GmbH
Medical and Health Services

Yu Qiu
Yu Qiu (Dec 15, 2023 17:01 GMT+8)

Yu Qiu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Dec 11, 2023 13:18 GMT+1)

Michael Mauermeir
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 **Gauze Swabs** Basic UDI-DI: 69415580gauzeswabEOIsJ2 69415580gauzeswabSTIsMV	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 2 **Non Woven Swabs** Basic UDI-DI: 69415580nonwovswabEOIsYC 69415580nonwovswabSTIs4A	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 3 **Drain Sponges** Basic UDI-DI: 69415580drainsponge1BM 69415580drainsponge2BP 69415580drainsponge3BR 69415580drainsponge4BT	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 4 **ABD Pads** Basic UDI-DI: 69415580ABDpadT7	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 002037 0010 Rev. 02; 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
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 5 **Fluffy Gauze Bandages** Basic UDI-DI: 69415580gauzeswab7XS	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 6 **Cotton-Filled Exodontia Sponges** Basic UDI-DI: 69415580exodontiaspongeCX	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 7 **Gauze Rolls** Basic UDI-DI: 69415580gauzeswab5XN	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 8 **Gauze Balls** Basic UDI-DI: 69415580gauzeballEOIs46 69415580gauzeballSTIs7Z	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2S 002037 0010 Rev. 02; 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
	☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 9 **Non Woven Balls** Basic UDI-DI: 69415580nonwovballEOIsJG	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 10 **Non Stick Pads** Basic UDI-DI: 69415580nonstickpadEO6G 69415580nonstickpadST84	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 11 **Eye Pads** Basic UDI-DI: 69415580eyepad1EG 69415580eyepad2EJ	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 12 **Triangular Bandages** Basic UDI-DI: 69415580triangular7H	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G2S 002037 0010 Rev. 02; 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
	☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 13 **Elastic Bandages** Basic UDI-DI: 69415580elasticbandage1WL 69415580elasticbandage2WN 69415580elasticbandage3WQ	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 14 **Adhesive Dressing** Basic UDI-DI: 69415580adhesivedress1BZ 69415580adhesivedress2C3	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 15 **Cotton Applicators** Basic UDI-DI: 69415580applicator19Q 69415580applicator29S	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 16 **Tongue Depressors** Basic UDI-DI:	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: Certificate # G2S 002037 0010 Rev. 02; 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
69415580tonguedepressorFU	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 17 **Medical Kits** Basic UDI-DI: 69415580medicalkit1VX 69415580medicalkit2VZ 69415580medicalkit3W3 69415580medicalkit4W5 69415580medicalkit5W7 69415580medicalkit6W9 69415580medicalkit7WB	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 # G2S 002037 0010 Rev. 02; NB# 0123
Device 18 **Gauze Swabs** **(without x-ray thread)** Basic UDI-DI: 69415580gauzeswab1EOAT 69415580gauzeswab1STCF	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 19 **Non Woven Swabs** **(without x-ray thread)** Basic UDI -DI: 69415580nonwovenswab1EOQZ 69415580nonwovenswab1STSM	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 20 **Gauze Swabs**	☐ Class III	☒ 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
(with x-ray thread) Basic UDI-DI: 69415580gauzeswabX1EOFC 69415580gauzeswabX1SF8	☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 21 **Non-Sterile Gauze Swabs (with x-ray thread)** Basic UDI-DI: 69415580gauzeswabX1NSGF	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 22 **Non-Sterile Gauze Swabs (without x-ray thread)** Basic UDI-DI: 69415580gauzeswab1NSBW	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 23 **Non Woven Swabs (with x-ray thread)** Basic UDI-DI: 69415580nonwovenswabXQP	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; 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
Device 24 **Non-Sterile Non Woven Swabs (with x-ray thread)** Basic UDI-DI: 69415580nonwovenswabXNSY2	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 25 **Non-Sterile Non Woven Swabs (without x-ray thread)** Basic UDI-DI: 69415580nonwovenswab1NSS4	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 26 **Gauze Balls (with x-ray thread)** Basic UDI-DI: 69415580gauzeballXEO4R 69415580gauzeballXS97	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 27 **Gauze Balls (without x-ray thread)** Basic UDI-DI: 69415580gauzeballEO76 69415580gauzeballST8S	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ Certification as follows: Certificate # G2 002037 0009 Rev. 02; 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
	☐ Class III implantable custom-made-device		
Device 28 **Non-Sterile Gauze Balls** **(with x-ray thread)** Basic UDI-DI: 69415580gauzeballXNS5U	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 29 **Non-Sterile Gauze Balls** **(without x-ray thread)** Basic UDI-DI: 69415580gauzeballNS89	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 30 **Non Woven Balls** **(with x-ray thread)** Basic UDI-DI: 69415580nonwovenballXGP	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 31 **Non Woven Balls** **(without x-ray thread)** Basic UDI-DI: 69415580nonwovenball7Z	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 002037 0009 Rev. 02; 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
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 32 **Non-Sterile Non Woven Balls (with x-ray thread)** Basic UDI-DI: 69415580nonwovenballXNSL2	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 33 **Non-Sterile Non Woven Balls (without x-ray thread)** Basic UDI-DI: 69415580nonwovenballNSVA	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 34 **Lap Sponges (with x-ray thread)** Basic UDI-DI: 69415580lapspongeXEOGF 69415580lapspongeXSTJ3	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 35 **Lap Sponges (without x-ray thread)** Basic UDI-DI: 69415580lapspongeKN	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 002037 0009 Rev. 02; 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
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 36 **Non-Sterile Lap Sponges (with x-ray thread)** Basic UDI-DI: 69415580lapspongeXNSHJ	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 37 **Non-Sterile Lap Sponges (without x-ray thread)** Basic UDI-DI: 69415580lapspongeNSJR	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 38 **OR Towel (with x-ray thread)** Basic UDI-DI: 69415580ORtowelXSJ	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 39 **OR Towel (without x-ray thread)** Basic UDI-DI:	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate # G2 002037 0009 Rev. 02; 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
69415580ORtowel3E	☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 40 **Non-Sterile OR Towel (with x-ray thread)** Basic UDI-DI: 69415580ORtowelXNSYL	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 41 **Non-Sterile OR Towel (without x-ray thread)** Basic UDI-DI: 69415580ORtowelNSS4	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 42 **Zig Zag Folded Gauze** Basic UDI-DI: 69415580gauzeswab3XJ	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 002037 0009 Rev. 02; NB# 0123
Device 43 **Sterile Paraffin Gauze Dressing** Basic UDI-DI:	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: Certificate # G2 002037 0009 Rev. 02; 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
69415580paraffingauze9Z	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 44 **Woundhook covers** Basic UDI-DI: 9415580woundhookcover56	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 45 **Non-Sterile Woundhook Covers** Basic UDI-DI: 69415580woundhookcovNSZR	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; NB# 0123
Device 46 **Medical Kits** Basic UDI-DI: 69415580medicalkitH8	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ 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 002037 0009 Rev. 02; 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
2023-12-11	713265109 | 713311920	Initial issue