

No.18 QiXing Road, Majiadian Town, 443200 Zhijiang City,
Hubei Province, P.R.C
Tel: 86 717 4211111 Fax: 86 717 4225499



Declaration of Conformity

Manufacturer: Allmed Medical Products Co., Ltd

Address: No.18 Qixing Road, Majiadian Town, 443200 Zhijiang City, Hubei province,
PEOPLE'S REPUBLIC OF CHINA

European Representative: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Sterile and non-sterile lap sponges (with or without x-ray thread)

UMDNS Code: 15085

Model Number: Please refer to List of CE-labeled Products.

Classification (MDD, Annex IX): II a

Classification Rule: 7

Conformity Assessment Route: MDD93/42/EEC Annex V

We herewith declare in our own responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

Medical Device Directive: The object of the declaration described above is in conformity with the Council Directive MDD 93/42/EEC.

Standard Applied: All applicable harmonised standard (published in the official journal of the European Communities).

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany

Identification number: 0123

(EC) Certificate(s): G2 002037 0009 Rev.02

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2012-8-17

Place, Date of Issue: Hubei, 2020-09-01

Confirmation Letter: CL 002037 0021 Rev.00

Expire date of CL: 2028-12-31

Signature: Wine Tian

Name: Mar. 15. 2024

General Manager of Quality

Position:



**Add value.
Inspire trust.**

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

Allmed Medical Products Co., Ltd
No.18 Qixing Road, Majiadian Town
443200 ZHIJIANG CITY, HUBEI PROVINCE
PEOPLE'S REPUBLIC OF CHINA

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

**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

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Certification Body for Medical Products
Ridlerstr. 65
80339 Munich
Germany

tuvsud.com/ps
Hotline: +49 89 50084-747





(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

TÜV SÜD Product Service GmbH
Medical and Health Services


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

Yu Qiu
Conformity Assessment Responsible (CARE)


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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 2 Non Woven Swabs Basic UDI-DI: 69415580nonwovswabEOIsYC 69415580nonwovswabSTIs4A	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 3 Drain Sponges Basic UDI-DI: 69415580drainsponge1BM 69415580drainsponge2BP 69415580drainsponge3BR 69415580drainsponge4BT	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 4 ABD Pads Basic UDI-DI: 69415580ABDpadT7	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		
Device 5 Fluffy Gauze Bandages Basic UDI-DI: 69415580gauzeswab7XS	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 6 Cotton-Filled Exodontia Sponges Basic UDI-DI: 69415580exodontiaspongeCX	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 7 Gauze Rolls Basic UDI-DI: 69415580gauzeswab5XN	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 8 Gauze Balls Basic UDI-DI: 69415580gauzeballEOIs46 69415580gauzeballSTIs7Z	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
	<input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		
Device 9 Non Woven Balls Basic UDI-DI: 69415580nonwovballEOIsJG	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 10 Non Stick Pads Basic UDI-DI: 69415580nonstickpadEO6G 69415580nonstickpadST84	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 11 Eye Pads Basic UDI-DI: 69415580eyepad1EG 69415580eyepad2EJ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 12 Triangular Bandages Basic UDI-DI: 69415580triangular7H	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
	<input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		
Device 13 Elastic Bandages Basic UDI-DI: 69415580elasticbandage1WL 69415580elasticbandage2WN 69415580elasticbandage3WQ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 14 Adhesive Dressing Basic UDI-DI: 69415580adhesivedress1BZ 69415580adhesivedress2C3	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 15 Cotton Applicators Basic UDI-DI: 69415580applicator19Q 69415580applicator29S	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 16 Tongue Depressors Basic UDI-DI:	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		
Device 17 Medical Kits Basic UDI-DI: 69415580medicalkit1VX 69415580medicalkit2VZ 69415580medicalkit3W3 69415580medicalkit4W5 69415580medicalkit5W7 69415580medicalkit6W9 69415580medicalkit7WB	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 002037 0010 Rev. 02; NB# 0123
Device 18 Gauze Swabs (without x-ray thread) Basic UDI-DI: 69415580gauzeswab1EOAT 69415580gauzeswab1STCF	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 20 Gauze Swabs	<input type="checkbox"/> Class III	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> 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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 23 Non Woven Swabs (with x-ray thread) Basic UDI-DI: 69415580nonwovenswabXQP	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 26 Gauze Balls (with x-ray thread) Basic UDI-DI: 69415580gauzeballXEO4R 69415580gauzeballXS97	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 27 Gauze Balls (without x-ray thread) Basic UDI-DI: 69415580gauzeballEO76 69415580gauzeballST8S	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
	<input type="checkbox"/> Class III implantable custom-made-device		
Device 28 Non-Sterile Gauze Balls (with x-ray thread) Basic UDI-DI: 69415580gauzeballXNS5U	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 30 Non Woven Balls (with x-ray thread) Basic UDI-DI: 69415580nonwovenballXGP	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 31 Non Woven Balls (without x-ray thread) Basic UDI-DI: 69415580nonwovenball7Z	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		
Device 32 Non-Sterile Non Woven Balls (with x-ray thread) Basic UDI-DI: 69415580nonwovenballXNSL2	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 34 Lap Sponges (with x-ray thread) Basic UDI-DI: 69415580lapspongeXEOGF 69415580lapspongeXSTJ3	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 35 Lap Sponges (without x-ray thread) Basic UDI-DI: 69415580lapspongeKN	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
	<input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		
Device 36 Non-Sterile Lap Sponges (with x-ray thread) Basic UDI-DI: 69415580lapspongeXNSHJ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 38 OR Towel (with x-ray thread) Basic UDI-DI: 69415580ORTowelXSJ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 39 OR Towel (without x-ray thread) Basic UDI-DI:	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		
Device 40 Non-Sterile OR Towel (with x-ray thread) Basic UDI-DI: 69415580ORtowelXNSYL	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 41 Non-Sterile OR Towel (without x-ray thread) Basic UDI-DI: 69415580ORtowelINSS4	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 42 Zig Zag Folded Gauze Basic UDI-DI: 69415580gauzeswab3XJ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 43 Sterile Paraffin Gauze Dressing Basic UDI-DI:	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		
Device 44 Woundhook covers Basic UDI-DI: 9415580woundhookcover56	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 45 Non-Sterile Woundhook Covers Basic UDI-DI: 69415580woundhookcovNSZR	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2 002037 0009 Rev. 02; NB# 0123
Device 46 Medical Kits Basic UDI-DI: 69415580medicalkitH8	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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