

Inspire trust.

TÜV SÜD Product Service GmbH. · Germany

Hubei Qianjiang Kingphar Medical Material Co., Ltd. Yuanguang Road 433100 Qianjiang PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of Our reference/name Tel. extension/Email Fax extension Date Page 045790 713269189,713309505,71330904 +86 21 6142 4344 2024-03-19 1 of 7 Xiongfei Fang Xiongfei.Fang@tuvsud.com

TÜV SÜD Product Service GmbH Confirmation Letter CL 045790 0033 Rev. 00

Reference: 713269189 | 713309505 | 71330904

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-000009051

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.

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 Welii

TÜV SÜD Product Service GmbH

tuvsud.com/ps

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Germany





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-045790-0033 Rev. 00

On behalf of the Notified Body TÜV SÜD Product Service GmbH, 2024-03-19

TÜV SÜD Product Service GmbH Medical and Health Services

Fang Xiongfei

Xiongfei Fang

Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH Medical and Health Services

Christian Ullmann 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-	MDR Device classification	If the MDR device is a substitute	MDD/AIMDD Certificate Refer-
DI (under MDR applica-	(as proposed by the manu-	device, identification of the corre-	ence(s) of the devices under MDR
tion)	facturer and verified during	sponding MDD/AIMDD device	application, and the NB Identifi-
D 1 1	application review)	SZ NI/A	cation
Device 1		⊠ N/A	☑ Certification as follows:
Gauze swab with X-Ray	☐ Class IIb implantable (non-		Certificate #G2 045790 0027 Rev.
(Basic UDI -DI:	exempted) □ Class IIb / Class IIb im-	or	01; NB# 0123
694878812001PV)		Udantification of the commenced	
	plantable (exempted) ⊠ Class IIa	☐ Identification of the correspond-	or
	☐ Class I devices in sterile	ing device under MDD/AIMDD Individual Article number:	☐ Evidence that a competent au-
	condition	marviduai Arucie number:	thority of a Member State had
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #1, CA# Evidence #2; CA#
Device 2	□ Class III	⊠ N/A	⊠ Certification as follows:
Lap sponges with X-Ray	☐ Class IIb implantable (non-	M IVA	Certificate #G2 045790 0027 Rev.
(Basic UDI -DI:	exempted)	or	01; NB# 0123
694878812002PX)	□ Class IIb / Class IIb im-	OI .	01, NB# 0123
0946766120021 A)	plantable (exempted)	☐ Identification of the correspond-	or
	⊠ Class IIa	ing device under MDD/AIMDD	OI .
	☐ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition	marvidai Article number.	thority of a Member State had
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device 3	□ Class III	⊠ N/A	☑ Certification as follows:
Lap sponges without X-	☐ Class IIb implantable (non-		Certificate #G2 045790 0027 Rev.
Ray	exempted)	or	01; NB# 0123
(Basic UDI -DI:	☐ Class IIb / Class IIb im-		01,1120120
694878812006Q7)	plantable (exempted)	☐ Identification of the correspond-	or
,	⊠ Class IIa	ing device under MDD/AIMDD	
	☐ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition		thority of a Member State had
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device 4	□ Class III	⊠ N/A	☑ Certification as follows:
Gauze ball with X-Ray	☐ Class IIb implantable (non-		Certificate #G2 045790 0027 Rev.
(Basic UDI -DI:	exempted)	or	01; NB# 0123
694878812003PZ)	☐ Class IIb / Class IIb im-		
	plantable (exempted)	☐ Identification of the correspond-	or
	⊠ Class IIa	ing device under MDD/AIMDD	
	☐ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition		thority of a Member State had



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding 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		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 5 Non-woven sponges with X-Ray (Basic UDI -DI: 694878812004Q3)	☐ 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	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☑ Certification as follows: Certificate #G2 045790 0027 Rev. 01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 6 Gauze swab without X-Ray (Basic UDI -DI: 694878812005Q5)	☐ 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	or □ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☑ Certification as follows: Certificate #G2 045790 0027 Rev. 01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 7 Gauze ball without X-Ray (Basic UDI -DI: 694878812007Q9)	□ Class III □ Class IIIb 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 or □ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☐ Certification as follows: Certificate #G2 045790 0027 Rev. 01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 8 Non-woven sponge without X-Ray (Basic UDI -DI: 694878812008QB)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition	 ☑ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: 	⊠ Certification as follows: Certificate #G2 045790 0027 Rev. 01; NB# 0123 or □ Evidence that a competent authority of a Member State had



Device name or Basic UDI-	MDR Device classification	If the MDR device is a substitute	MDD/AIMDD Certificate Refer-
DI (under MDR applica-	(as proposed by the manu-	device, identification of the corre-	ence(s) of the devices under MDR
tion)	facturer and verified during	sponding MDD/AIMDD device	application, and the NB Identifi-
	application review)		cation
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device 9	□ Class III	⊠ N/A	☑ Certification as follows:
Dressing Kit	☐ Class IIb implantable (non-		Certificate #G2 045790 0027 Rev.
(Basic UDI -DI:	exempted)	or	01; NB# 0123
694878812012Q2)	☐ Class IIb / Class IIb im-		
	plantable (exempted)	☐ Identification of the correspond-	or
	⊠ Class IIa	ing device under MDD/AIMDD	
	☐ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition		thority of a Member State had
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device 10	□ Class III	⊠ N/A	☑ Certification as follows:
Adhesive Wound Dressing	☐ Class IIb implantable (non-		Certificate #G2 045790 0027 Rev.
(Basic UDI -DI:	exempted)	or	01; NB# 0123
694878812013Q4)	☐ Class IIb / Class IIb im-		
ζ,	plantable (exempted)	☐ Identification of the correspond-	or
	⊠ Class IIa	ing device under MDD/AIMDD	
	☐ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition		thority of a Member State had
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device 11	□ Class III	⊠ N/A	☑ Certification as follows:
Abdominal Dressing Pad	☐ Class IIb implantable (non-		Certificate #G2 045790 0027 Rev.
(Basic UDI -DI:	exempted)	or	01; NB# 0123
694878812014Q6)	☐ Class IIb / Class IIb im-		
	plantable (exempted)	☐ Identification of the correspond-	or
	⊠ Class IIa	ing device under MDD/AIMDD	
	☐ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition		thority of a Member State had
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device 12	□ Class III	⊠ N/A	☑ Certification as follows:
Sterile Gauze Swab with-	☐ Class IIb implantable (non-		Certificate #G2S 045790 0026
out X-ray	exempted)	or	Rev. 01; NB# 0123
(Basic UDI -DI:	☐ Class IIb / Class IIb im-		
694878811*005E4)	plantable (exempted)	☐ Identification of the correspond-	or
,	□ Class IIa	ing device under MDD/AIMDD	
	☐ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition		thority of a Member State had



Device name or Basic UDI-	MDR Device classification	If the MDR device is a substitute	MDD/AIMDD Certificate Refer-
DI (under MDR applica-	(as proposed by the manu-	device, identification of the corre-	ence(s) of the devices under MDR
tion)	facturer and verified during	sponding MDD/AIMDD device	application, and the NB Identifi-
	application review)		cation
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device 13	□ Class III	⊠ N/A	☑ Certification as follows:
Sterile Gauze Ball without	☐ Class IIb implantable (non-		Certificate #G2S 045790 0026
X-ray	exempted)	or	Rev. 01; NB# 0123
(Basic UDI -DI:	☐ Class IIb / Class IIb im-		
694878811*006E6)	plantable (exempted)	☐ Identification of the correspond-	or
	□ Class IIa	ing device under MDD/AIMDD	
	☑ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition		thority of a Member State had
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device 14	□ Class III	⊠ N/A	☑ Certification as follows:
Sterile Gauze Bandage	☐ Class IIb implantable (non-		Certificate #G2S 045790 0026
(Basic UDI -DI:	exempted)	or	Rev. 01; NB# 0123
694878811*002DW)	☐ Class IIb / Class IIb im-		,
,	plantable (exempted)	☐ Identification of the correspond-	or
	□ Class IIa	ing device under MDD/AIMDD	
	☐ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition		thority of a Member State had
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device 15	□ Class III	⊠ N/A	☑ Certification as follows:
Sterile elastic bandage	☐ Class IIb implantable (non-		Certificate #G2S 045790 0026
(Basic UDI -DI:	exempted)	or	Rev. 01; NB# 0123
694878811*007E8)	☐ Class IIb / Class IIb im-	01	10.1.01,1120120
0,10,0011 00,20,	plantable (exempted)	☐ Identification of the correspond-	or
	□ Class IIa	ing device under MDD/AIMDD	
	☐ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition	marvidua / muele namber.	thority of a Member State had
			granted acc. MDR, Art.59 (1) or
	☐ Class I devices with measuring function		
	uring function		Art.97 (1)
	uring function ☐ Class III implantable cus-		Art.97 (1) Evidence #1; CA#
Device 16	uring function ☐ Class III implantable custom-made-device	⊠ N/A	Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 16 Sterile Non-woven Swah	uring function ☐ Class III implantable custom-made-device ☐ Class III	⊠ N/A	Art.97 (1) Evidence #1; CA# Evidence #2; CA# ☑ Certification as follows:
Sterile Non-woven Swab	uring function ☐ Class III implantable custom-made-device ☐ Class III ☐ Class IIb implantable (non-		Art.97 (1) Evidence #1; CA# Evidence #2; CA# ☑ Certification as follows: Certificate #G2S 045790 0026
Sterile Non-woven Swab without X-Ray	uring function ☐ Class III implantable custom-made-device ☐ Class III ☐ Class IIb implantable (non-exempted)	⊠ N/A or	Art.97 (1) Evidence #1; CA# Evidence #2; CA# ☑ Certification as follows:
Sterile Non-woven Swab without X-Ray (Basic UDI -DI:	uring function □ Class III implantable custom-made-device □ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb im-	or	Art.97 (1) Evidence #1; CA# Evidence #2; CA# ☑ Certification as follows: Certificate #G2S 045790 0026 Rev. 01; NB# 0123
Sterile Non-woven Swab without X-Ray	uring function Class III implantable custom-made-device Class III Class III implantable (non-exempted) Class IIb / Class IIb implantable (exempted)	or ☐ Identification of the correspond-	Art.97 (1) Evidence #1; CA# Evidence #2; CA# ☑ Certification as follows: Certificate #G2S 045790 0026
Sterile Non-woven Swab without X-Ray (Basic UDI -DI:	uring function □ Class III implantable custom-made-device □ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb im-	or	Art.97 (1) Evidence #1; CA# Evidence #2; CA# ☑ Certification as follows: Certificate #G2S 045790 0026 Rev. 01; NB# 0123



Device name or Basic UDI-	MDR Device classification	If the MDR device is a substitute	MDD/AIMDD Certificate Refer-
DI (under MDR applica-	(as proposed by the manu-	device, identification of the corre-	ence(s) of the devices under MDR
tion)	facturer and verified during	sponding MDD/AIMDD device	application, and the NB Identifi-
	application review)		cation
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device 17	☐ Class III	⊠ N/A	☑ Certification as follows:
Sterile Absorbent	☐ Class IIb implantable (non-		Certificate #G2S 045790 0026
Gauze(Rolled)	exempted)	or	Rev. 01; NB# 0123
(Basic UDI -DI:	☐ Class IIb / Class IIb im-		
694878811*003DY)	plantable (exempted)	☐ Identification of the correspond-	or
	□ Class IIa	ing device under MDD/AIMDD	
	□ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition		thority of a Member State had
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device 18	☐ Class III	⊠ N/A	☑ Certification as follows:
Sterile Absorbent Cotton	☐ Class IIb implantable (non-		Certificate #G2S 045790 0026
(Basic UDI -DI:	exempted)	or	Rev. 01; NB# 0123
694878811*001DU)	☐ Class IIb / Class IIb im-		
	plantable (exempted)	☐ Identification of the correspond-	or
	□ Class IIa	ing device under MDD/AIMDD	
	□ Class I devices in sterile	Individual Article number:	☐ Evidence that a competent au-
	condition		thority of a Member State had
	☐ Class I devices with meas-		granted acc. MDR, Art.59 (1) or
	uring function		Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#

Table 2: Devices covered by this letter and for which $T\ddot{U}V$ $S\ddot{U}D$ Product Service GmbH is \underline{NOT} responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding 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
2024-03-19	713269189 713309505 71330904	Initial issue