



# CE SERTIFIKATAS

## Gamybos kokybės užtikrinimo sistema

Medicinos prietaisų direktyva 93/42/EEB, Priedas V

(IIa, IIb ar III klasės prietaisai)

Nr. G2 045879 0021 Rev. 01

**Gamintojas:** Jiangu Kanghua Medical Equipment  
Co., Ltd.  
Sanhekou  
213115 Changzhou  
KINIJOS LIAUDIES RESPUBLIKA

**Atstovas** Jiangu Kanghua Medical Equipment  
Co., Ltd.  
Sanhekou  
213115 Changzhou  
KINIJOS LIAUDIES RESPUBLIKA

**Produkto kategorija(os):** Vienkartiniai švirkštai,  
Vienkartinės infuzinės sistemos,  
Vienkartinės transfuzinės sistemos,  
Intraveninės adatos vienkartinės,  
Sterilios hipoderminės adatos vienkartinės,  
Vienkartiniai insulininiai švirkštai,  
Vienkartiniai tuberkulininiai švirkštai,  
Vienkartinės adatos insulino penams

Sertifikavimo įstaiga TÜV SÜD Product Service GmbH patvirtina, kad paminėtasis gamintojas įdiegė kokybės užtikrinimo sistemą atitinkamų prietaisų/prietaisų kategorijų gamybai ir galutiniam patikrinimui pagal medicinos prietaisų direktyvos 93/42/EEB V Priedą. Ši kokybės užtikrinimo sistema atitinka šios direktyvos sąlygas ir turi būti periodiškai peržiūrima. IIb ir III klasės produktams yra privalomas papildomas III priedo sertifikatas. Taip pat žr. lapo apačioje.

**Protokolo Nr.** SH19165EXT01

**Galioja nuo:** 2019-09-30

**Galioja iki:** 2024-05-26

**Data,** 2019-09-30 /parašas/  
Stefan Preis

TÜV SÜD Product Service GmbH yra notifikuota įstaiga, identifikacijos Nr. 0123.



**Add value.  
Inspire trust.**

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

Jiangsu Kanghua Medical Equipment  
Co., Ltd.  
Sanhekou  
213115 Changzhou  
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	E-mail	Tel. extension	Date	Page
027625	SH2416501	medical_devices@tuvsud.com	---	2024-05-15	1 of 9

### **TÜV SÜD Product Service GmbH Confirmation Letter**

**CL 045879 0026 Rev. 00**

**Reference: SH2416501 | 713334498**

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-000033842**

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:**  
Dr. Walter Reithmaier (CEO)  
Patrick van Welij

**TÜV SÜD Product Service GmbH**  
Application Review  
Ridlerstr. 65  
80339 Munich  
Germany

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





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\\_045879\\_0026\\_Rev.\\_00](http://www.tuvsud.com/ps-cert?q=cert:CL_045879_0026_Rev._00)

In case of inquiries please contact: [medical\\_devices@tuvsud.com](mailto:medical_devices@tuvsud.com)

On behalf of the Notified Body TÜV SÜD Product Service GmbH,  
2024-05-15

TÜV SÜD Product Service GmbH  
Medical and Health Services

TÜV SÜD Product Service GmbH  
Medical and Health Services



Jie Pan  
Conformity Assessment Responsible (CARE)

Konrad Fackler  
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
<b>Sterile Vagina Dilator for Single Use</b>  <b>Basic UDI-DI:</b> 693549170600K8	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 045879 0019 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Disposable Feeding Syringes</b>  <b>Basic UDI-DI:</b> 693549171800KR	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 045879 0019 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Urine Collection Bags</b>  <b>Basic UDI-DI:</b> 693549170500K3	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 045879 0019 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



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
<b>Disposable Catheter Tip Syringes</b>  <b>Basic UDI-DI:</b> 693549172300K7 693549171200JT	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2MS 045879 0017 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Disposable Syringes without Needle</b>  <b>Basic UDI-DI:</b> 693549171500KA 693549172500KH	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2MS 045879 0017 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Disposable Tuberculin Syringes without Needle</b>  <b>Basic UDI-DI:</b> 693549171700KL	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2MS 045879 0017 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



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
<b>Disposable Insulin Syringes without Needle</b>  <b>Basic UDI-DI:</b> 693549171600KF	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2MS 045879 0017 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Disposable Syringes</b>  <b>Basic UDI-DI:</b> 693549170800KJ 693549172200K2	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Disposable Infusion Sets</b>  <b>Basic UDI-DI:</b> 693549170900KP	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



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
<b>Disposable Transfusion Sets</b>  <b>Basic UDI-DI:</b> 693549171000JH 693549172400KC	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Burette-type Infusion Sets for Single Use</b>  <b>Basic UDI-DI:</b> 693549170300JR	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Sterile Hypodermic Needles for Single Use</b>  <b>Basic UDI-DI:</b> 693549170400JW	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



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
<b>Disposable Insulin Syringes</b>  <b>Basic UDI-DI:</b> 693549170100JF	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Disposable Tuberculin Syringes</b>  <b>Basic UDI-DI:</b> 693549170200JL	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Disposable Insulin Pen Needles</b>  <b>Basic UDI-DI:</b> 693549171300JY	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



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
<b>Intravenous Needles for Single Use</b>  <b>Basic UDI-DI:</b> 693549170700KD	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Safety Syringes</b>  <b>Basic UDI-DI:</b> 693549171900KW	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
<b>Auto-Disable Syringes</b>  <b>Basic UDI-DI:</b> 693549172000JQ	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



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
<b>Auto-Disable Safety Syringes</b>  <b>Basic UDI-DI:</b> 693549172100JV	<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  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G2 045879 0021 Rev. 01 NB #0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)

**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
2024-05-15	SH2416501   713334498	Initial issue

