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

KD Medical GmbH Hospital Products Charlottenstrasse 65 10117 Berlin

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
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	ΤÜV	SÜD Product Service Confirmation Letter	GmbH		

CL 037875 0052 Rev. 00

Reference: 713315883

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: DE-MF-000006773

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 <u>not</u> 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 Welij TÜV SÜD Product Service GmbH Zertifizierstelle für Medizinprodukte / Certification Body for Medical Products 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see <u>www.tuvsud.com/ps-cert?q=cert:CL 037875 0052 Rev. 00</u>

In case of inquiries please contact medical devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH, 2024-03-25

TÜV SÜD Product Service GmbH Medical and Health Services

No Duado Katarzyna Dziadosz (25. März 2024 17.45 GMT+1)

Katarzyna Dziadosz Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH Medical and Health Services

Franziska Eckert 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 ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
4031881G11-03alsQD	□ Class III □ Class IIb implantable	⊠ N/A	☑ Certification as follows: G2S 037875 0045 Rev. 00
KD-CAP	(non-exempted) □ Class IIb / Class IIb im-	or	or
Individual article num- ber:	plantable (exempted) □ Class IIa ⊠ Class I devices in sterile	 Identification of the corre- sponding device under MDD/AIMDD 	□ N/A - Device did not require a Notified Body certificate un-
762530	condition □ Class I devices with	Individual Article number:	der Directives
	measuring function		or
	custom-made-device □ Class I reusable surgical instruments		 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#
4031881G11-01IsMJ	□ Class III □ Class IIb implantable	⊠ N/A	Certification as follows:
KD-FINE	 □ Class IIb Implantable (non-exempted) □ Class IIb / Class IIb im- 	or	G2S 037875 0045 Rev. 00
Individual article num- ber:	plantable (exempted) □ Class IIa ⊠ Class I devices in sterile	 Identification of the corre- sponding device under MDD/AIMDD 	□ N/A - Device did not require a Notified Body certificate un-
907962 907979	condition □ Class I devices with	Individual Article number:	der Directives
917145	measuring function		or
	custom-made-device □ Class I reusable surgical instruments		 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#
4031881G11-01IsMJ	□ Class III □ Class IIb implantable	⊠ N/A	 ☑ Certification as follows: G2S 037875 0045 Rev. 00
KD-FINE BLUNT	 □ Class IIb Implantable (non-exempted) □ Class IIb / Class IIb im- 	or	G25 037875 0045 Rev. 00
Individual article num- ber:	plantable (exempted) □ Class IIa ⊠ Class I devices in sterile	 Identification of the corre- sponding device under MDD/AIMDD 	□ N/A - Device did not require a Notified Body certificate un-
909294 909300A	condition	Individual Article number:	der Directives



Device name or Basic UDI-DI (under MDR ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
910597 910603A 920282 920299	 □ Class I devices with measuring function □ Class III implantable custom-made-device □ Class I reusable surgical instruments 		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#
4031881G11-04blms2H KD-JECT Individual article num- ber:	 □ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb implantable (exempted) □ Class IIa ⊠ Class I devices in sterile 	 N/A or Identification of the corresponding device under MDD/AIMDD 	 Certification as follows: G2S 037875 0045 Rev. 00 or N/A - Device did not require a Notified Body certificate un-
802205 805206 810200 820209 805206C	condition Class I devices with measuring function Class III implantable custom-made-device Class I reusable surgical instruments	Individual Article number:	der Directives 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#
4031881G11-02blmsZQ KD-JECT E	□ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb im-	N/A or	 ☑ Certification as follows: G2MS 037875 0046 Rev. 00 or
Individual article num- ber: 875674 875681 875698 875704 875711 875728 876381	plantable (exempted) □ Class IIa ⊠ Class I devices in sterile condition ⊠ Class I devices with measuring function □ Class III implantable custom-made-device □ Class I reusable surgical instruments	☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	 N/A - Device did not require a Notified Body certificate un- der Directives 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#
4031881G11-04alms2A KD-JECT III	 □ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb implantable (exempted) 	⊠ N/A or	 Certification as follows: G2S 037875 0045 Rev. 00 or



Device name or Basic UDI-DI (under MDR ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
Individual article num- ber: 831854 831861 831878 831878 831885 831885 831892 870648 870662 870662 870686 875513 831885E	 □ Class IIa □ Class I devices in sterile condition □ Class I devices with measuring function □ Class III implantable custom-made-device □ Class I reusable surgical instruments 	☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	 N/A - Device did not require a Notified Body certificate un- der Directives 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#
4031881G11-04dlms2X KD-JECT III Individual article num- ber: 870648S	 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 Class I reusable surgical instruments 	 ☑ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: 	 Certification as follows: G2S 037875 0045 Rev. 00 or N/A - Device did not require a Notified Body certificate un- der Directives 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#
4031881G11-04elms36 KD-JECT III Individual article num- ber: 832073 870822 876749	 □ 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 □ Class I reusable surgical instruments 	 N/A or □ Identification of the corresponding device under MDD/AIMDD Individual Article number: 	Evidence #2; CA# ☑ Certification as follows: G2S 037875 0045 Rev. 00 or □ N/A - Device did not require a Notified Body certificate un- der Directives or □ 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 ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
			Evidence #1; CA#
			Evidence #2; CA#
4031881G11-04flms3D	□ Class III	⊠ N/A	☑ Certification as follows:
	□ Class IIb implantable		G2S 037875 0045 Rev. 00
KD-JECT III	(non-exempted)	or	
	□ Class IIb / Class IIb im-		or
Individual article num-	plantable (exempted)	□ Identification of the corre-	
ber:	□ Class IIa	sponding device under	□ N/A - Device did not require
	Class I devices in sterile	MDD/AIMDD	a Notified Body certificate un-
831908	condition	Individual Article number:	der Directives
831915	□ Class I devices with		
831922	measuring function		or
831939	□ Class III implantable		
831946	custom-made-device		□ Evidence that a competent
865613	Class I reusable surgical		authority of a Member State
870761	instruments		had granted acc. MDR, Art.59
870785			(1) or Art.97 (1)
872109			Evidence #1; CA#
			Evidence #2; CA#
4031881G11-02almsZH	□ Class III	⊠ N/A	☑ Certification as follows:
	□ Class IIb implantable		G2MS 037875 0046 Rev. 00
KD-JECT O	(non-exempted)	or	
	□ Class IIb / Class IIb im-		or
Individual article num-	plantable (exempted)	□ Identification of the corre-	
ber:	Class IIa	sponding device under	□ N/A - Device did not require
	☑ Class I devices in sterile	MDD/AIMDD	a Notified Body certificate un-
870846	condition	Individual Article number:	der Directives
870853	☑ Class I devices with		
870860	measuring function		or
870877	□ Class III implantable		
873243	custom-made-device		□ Evidence that a competent
	□ Class I reusable surgical		authority of a Member State
	instruments		had granted acc. MDR, Art.59
			(1) or Art.97 (1)
			Evidence #1; CA#
			Evidence #2; CA#
4031881G11-04alms2A	□ Class III	⊠ N/A	☑ Certification as follows:
	□ Class IIb implantable		G2S 037875 0045 Rev. 00
KDM syringes	(non-exempted)	or	
	□ Class IIb / Class IIb im-		or
Individual article num-	plantable (exempted)	□ Identification of the corre-	
ber:	□ Class IIa	sponding device under	□ N/A - Device did not require
	☑ Class I devices in sterile	MDD/AIMDD	a Notified Body certificate un-
916896	condition	Individual Article number:	der Directives
916902	□ Class I devices with		
916919	measuring function		or
916926			



Device name or Basic UDI-DI (under MDR ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
	 □ Class III implantable custom-made-device □ Class I reusable surgical instruments 		 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#
4031881G11-06alsR2 KD-SPIKE Individual article num- ber: 772980	 □ 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 II implantable custom-made-device □ Class I reusable surgical instruments 	 ☑ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: 	 Certification as follows: G2S 037875 0045 Rev. 00 or N/A - Device did not require a Notified Body certificate under Directives 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#
4031881G11-06bIsR7 KD-SPIKE Individual article num- ber: 775714 775776 775721 775783 775738 775738 775790 775837 775899 775805 775844 775851	 □ 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 II implantable custom-made-device □ Class I reusable surgical instruments 	 ☑ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: 	 Certification as follows: G2S 037875 0045 Rev. 00 or N/A - Device did not require a Notified Body certificate under Directives 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#
4031881G11-03blsQJ KD-STOP Individual article num- ber:	 □ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb implantable (exempted) □ Class IIa 	⊠ N/A or	 ☑ Certification as follows: G2S 037875 0045 Rev. 00 or



Device name or Basic UDI-DI (under MDR ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
	⊠ Class I devices in sterile	□ Identification of the corre-	□ N/A - Device did not require
772577	condition	sponding device under	a Notified Body certificate un-
772584	□ Class I devices with	MDD/AIMDD	der Directives
772614	measuring function	Individual Article number:	
	□ Class III implantable custom-made-device		or
	Class I reusable surgical		□ Evidence that a competent
	instruments		authority of a Member State
			had granted acc. MDR, Art.59
			(1) or Art.97 (1)
			Evidence #1; CA#
			Evidence #2; CA#



Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
Not applicable All devices in scope are subject to Table 1	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
2024-03-25	713315883	Initial issue



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

KD Medical GmbH Hospital Products Charlottenstrasse 65 10117 Berlin

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CL 037875 0052 Rev. 01

Reference: 713315883

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: DE-MF-000006773

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.
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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 Zertifizierstelle für Medizinprodukte / Certification Body for Medical Products 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see <u>www.tuvsud.com/ps-cert?q=cert:CL 037875 0052 Rev. 01</u>

In case of inquiries please contact medical devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH, 2024-04-02

TÜV SÜD Product Service GmbH Medical and Health Services

No Duado Katarzyna Dziadosz (2. April 2024 16:03 GMT+2)

Katarzyna Dziadosz Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH Medical and Health Services

Franziska Eckert 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 ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
4031881G11-03alsQD KD-CAP	□ Class III □ Class IIb implantable (non-exempted)	⊠ N/A or	 ☑ Certification as follows: Certificate # G2S 037875 0045 Rev. 00; NB # 0123
Individual article num- ber: 762530	 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 Class I reusable surgical instruments 	☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	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#
4031881G11-01IsMJ KD-FINE	□ Class III □ Class IIb implantable (non-exempted)	⊠ N/A or	 ☑ Certification as follows: Certificate # G2S 037875 0045 Rev. 00; NB # 0123
Individual article num- ber: 907962 907979 917145	 Class IIb / Class IIb implantable (exempted) Class IIa Class I devices in sterile condition Class I devices with measuring function Class II implantable custom-made-device Class I reusable surgical instruments 	☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	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#
4031881G11-01IsMJ KD-FINE BLUNT Individual article num-	 □ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb implantable (exempted) □ Class IIa 	 ☑ N/A or □ Identification of the corre- 	 ☑ Certification as follows: Certificate # G2S 037875 0045 Rev. 00; NB # 0123 or
ber: 909294 909300A 910597 910603A 920282 920299	 Class IIa Class I devices in sterile condition Class I devices with measuring function Class III implantable custom-made-device Class I reusable surgical instruments 	sponding device under MDD/AIMDD Individual Article number:	□ 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 name or Basic UDI-DI (under MDR ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
4031881G11-04blms2H	□ Class III □ Class IIb implantable	⊠ N/A	☑ Certification as follows: Certificate # G2S 037875 0045
KD-JECT	(non-exempted) □ Class IIb / Class IIb im-	or	Rev. 00; NB # 0123
Individual article num-	plantable (exempted)	□ Identification of the corre-	or
ber:	□ Class IIa ⊠ Class I devices in sterile	sponding device under MDD/AIMDD	□ Evidence that a competent
802205	condition	Individual Article number:	authority of a Member State
805206	□ Class I devices with		had granted acc. MDR, Art.59
810200	measuring function		(1) or Art.97 (1)
820209	Class III implantable		Evidence #1; CA#
805206C	custom-made-device Class I reusable surgical instruments		Evidence #2; CA#
4031881G11-02blmsZQ KD-JECT E	□ Class III □ Class IIb implantable (non-exempted)	⊠ N/A	 Certification as follows: Certificate # G2MS 037875 0046 Rev. 00; NB # 0123
	□ Class IIb / Class IIb im-		
Individual article num-	plantable (exempted)	□ Identification of the corre-	or
ber:	□ Class IIa	sponding device under	
	⊠ Class I devices in sterile	MDD/AIMDD	Evidence that a competent
875674	condition	Individual Article number:	authority of a Member State
875681	⊠ Class I devices with		had granted acc. MDR, Art.59
875698	measuring function		(1) or Art.97 (1)
875704	Class III implantable		Evidence #1; CA#
875711	custom-made-device		Evidence #2; CA#
875728	Class I reusable surgical		
876381	instruments		
4031881G11-04alms2A	□ Class III □ Class IIb implantable	⊠ N/A	☑ Certification as follows: Certificate # G2S 037875 0045
KD-JECT III	(non-exempted) □ Class IIb / Class IIb im-	or	Rev. 00; NB # 0123
Individual article num-	plantable (exempted)	□ Identification of the corre-	or
ber:	□ Class IIa	sponding device under	
	☑ Class I devices in sterile	MDD/AIMDD	□ Evidence that a competent
831854	condition	Individual Article number:	authority of a Member State
831861	□ Class I devices with		had granted acc. MDR, Art.59
831878	measuring function		(1) or Art.97 (1)
831878E	□ Class III implantable		Evidence #1; CA#
831885	custom-made-device		Evidence #2; CA#
831892	□ Class I reusable surgical		
870648	instruments		
870662			
870686			
875513			
831885E			



Device name or Basic UDI-DI (under MDR ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
4031881G11-04dlms2X KD-JECT III Individual article num-	 □ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb implantable (exempted) 	 ☑ N/A or □ Identification of the corre- 	Certification as follows: Certificate # G2S 037875 0045 Rev. 00; NB # 0123
ber: 870648S	 □ Class IIa ⊠ Class I devices in sterile condition □ Class I devices with measuring function □ Class II implantable custom-made-device □ Class I reusable surgical instruments 	sponding device under MDD/AIMDD Individual Article number:	 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#
4031881G11-04elms36 KD-JECT III	□ Class III □ Class IIb implantable (non-exempted)	⊠ N/A or	 ☑ Certification as follows: Certificate # G2S 037875 0045 Rev. 00; NB # 0123
Individual article num- ber:	 □ Class IIb / Class IIb im- plantable (exempted) □ Class IIa ⊠ Class I devices in sterile 	□ Identification of the corre- sponding device under MDD/AIMDD	or □ Evidence that a competent
832073 870822 832059 876749	condition Class I devices with measuring function Class III implantable custom-made-device Class I reusable surgical instruments	Individual Article number:	authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4031881G11-04flms3D KD-JECT III	 □ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb im- 	⊠ N/A or	 ☑ Certification as follows: Certificate # G2S 037875 0045 Rev. 00; NB # 0123
Individual article num- ber: 831908	plantable (exempted) □ Class IIa ⊠ Class I devices in sterile condition	 Identification of the corre- sponding device under MDD/AIMDD Individual Article number: 	or □ Evidence that a competent authority of a Member State
831915 831922 831939 831946 865613 870761 870785 872109	 Class I devices with measuring function Class III implantable custom-made-device Class I reusable surgical instruments 		had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4031881G11-02almsZH KD-JECT O	Class III Class IIb implantable (non-exempted)	⊠ N/A	 Certification as follows: Certificate # G2MS 037875 0046 Rev. 00; NB # 0123



Device name or Basic UDI-DI (under MDR ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
Individual article num- ber: 870846 870853 870860 870877 873243	 □ 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 □ Class I reusable surgical instruments 	 Identification of the corre- sponding device under MDD/AIMDD Individual Article number: 	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#
4031881G11-04alms2A	□ Class III □ Class IIb implantable	⊠ N/A	☑ Certification as follows: Certificate # G2S 037875 0045
KDM syringes	(non-exempted) □ Class IIb / Class IIb im-	or	Rev. 00; NB # 0123
Individual article num- ber:	plantable (exempted) □ Class IIa ⊠ Class I devices in sterile	 Identification of the corre- sponding device under MDD/AIMDD 	or □ Evidence that a competent
916896 916902 916919	condition □ Class I devices with measuring function	Individual Article number:	authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
916926	 Class III implantable custom-made-device Class I reusable surgical instruments 		Evidence #1; CA# Evidence #2; CA#
4031881G11-06alsR2 KD-SPIKE	□ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb im-	⊠ N/A or	 ☑ Certification as follows: Certificate # G2S 037875 0045 Rev. 00; NB # 0123
Individual article num- ber:	 □ Class IIb / Class IIb / III- plantable (exempted) □ Class IIa ⊠ Class I devices in sterile 	Identification of the corre- sponding device under MDD//IMDD	or □ Evidence that a competent
772980	 Class I devices in stellie condition Class I devices with measuring function Class III implantable custom-made-device Class I reusable surgical instruments 	MDD/AIMDD Individual Article number:	authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4031881G11-06blsR7	□ Class III □ Class IIb implantable	⊠ N/A	☑ Certification as follows: Certificate # G2S 037875 0045
KD-SPIKE	(non-exempted) □ Class IIb / Class IIb im-	or	Rev. 00; NB # 0123
Individual article num- ber:	plantable (exempted) □ Class IIa ⊠ Class I devices in sterile	☐ Identification of the corre- sponding device under MDD/AIMDD	or □ Evidence that a competent
775714	condition	Individual Article number:	authority of a Member State



Device name or Basic UDI-DI (under MDR ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
775776 775721 775783 775738	 □ Class I devices with measuring function □ Class III implantable custom-made-device 		had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
775790 775837 775899 775905 775844	□ Class I reusable surgical instruments		
775851 4031881G11-03blsQJ		⊠ N/A	Certification as follows:
KD-STOP	□ Class IIb implantable (non-exempted) □ Class IIb / Class IIb im-	or	Certificate # G2S 037875 0045 Rev. 00; NB # 0123
Individual article num- ber:	plantable (exempted) □ Class IIa ⊠ Class I devices in sterile	Identification of the corre- sponding device under MDD/AIMDD	or □ Evidence that a competent
772577 772584	condition □ Class I devices with	Individual Article number:	authority of a Member State had granted acc. MDR, Art.59
772614	measuring function Class III implantable custom-made-device Class I reusable surgical instruments		(1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR ap- plication)	MDR Device classifica- tion (as proposed by the manufacturer and veri- fied during application review)	If the MDR device is a substi- tute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Ref- erence(s) of the devices un- der MDR application, and the NB Identification
Not applicable All devices in scope are subject to Table 1	N/A	N/A	N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference tracea- ble to each version of the letter	Action
2024-03-25	713315883	Initial issue
2024-04-02	713315883	Correction of article numbers under Basic UDI-DI 4031881G11- 04eIms36 (addition of article number 832059) and clerical errors