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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
	713330445_CL	Katarzyna.dziadosz@tuvsuc	l.com	2024-04-11	1 of 21

## TÜV SÜD Product Service GmbH Confirmation Letter CL 037875 0054 Rev. 00

Reference: 713330445\_CL

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-000007458

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.

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 Ridlerstr. 65 80339 Munich Germany tuvsud.com/ps Hotline: +49 89 50084-747





- 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.
   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 0054 Rev. 00</u>

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH, 2024-04-11

TÜV SÜD Product Service GmbH Medical and Health Services

d. Diadon a Dziadosz (11. April 2024 13:53 GMT+2)

Katarzyna Dziadosz Conformity Assessment Responsible (CARE) TÜV SÜD Product Service GmbH Medical and Health Services

Claus Matthias Mumme 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 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 Refer- ence(s) of the devices under MDR application, and the NB Identification
4031881G10-08bHaX6	□ Class III	⊠ N/A	Certification as follows:
	Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-DRIP	exempted)	or	or
	□ Class IIb / Class IIb im-		
Individual article number:	plantable (exempted)	□ Identification of the correspond-	□ N/A - Device did not require a
430224	🖾 Class IIa	ing device under MDD/AIMDD	Notified Body certificate under
430231	□ Class I devices in sterile	Individual Article number:	Directives
430255	condition	In case of transfer identifier accord-	
430262	$\Box$ Class I devices with meas-	ing to former notified body	or
430279	uring function		
430286	□ Class III implantable cus- tom-made-device		Evidence that a competent au-
430293			thority of a Member State had granted acc. MDR, Art.59 (1) or
	□ Class I reusable surgical instruments		Art.97 (1)
	mstruments		Evidence #1; CA#
			Evidence #2; CA#
4031881G10-08IIaLU	Class III	🖾 N/A	Certification as follows:
	□ Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-DRIP	exempted)	or	or
	□ Class IIb / Class IIb im-		
Individual article number:	plantable (exempted)	□ Identification of the correspond-	□ N/A - Device did not require a
430415	🖾 Class IIa	ing device under MDD/AIMDD	Notified Body certificate under
430422	□ Class I devices in sterile	Individual Article number:	Directives
430200	condition	In case of transfer identifier accord-	
430446	□ Class I devices with meas- uring function	ing to former notified body	or
	□ Class III implantable cus- tom-made-device		□ Evidence that a competent au- thority of a Member State had
	□ Class I reusable surgical instruments		granted acc. MDR, Art.59 (1) or Art.97 (1)
			Evidence #1; CA#
			Evidence #2; CA#
4031881G10-07aHaWL	□ Class III	⊠ N/A	$\boxtimes$ Certification as follows:
KD-FIX	□ Class IIb implantable (non- exempted)	or	G1 037875 0044 Rev. 01
	□ Class IIb / Class IIb im-		or
Individual article number:	plantable (exempted)	□ Identification of the correspond-	
762141M	⊠ Class IIa	ing device under MDD/AIMDD	□ N/A - Device did not require a
762165M	□ Class I devices in sterile	Individual Article number:	Notified Body certificate under
762172M	condition	In case of transfer identifier accord-	Directives
762189M	$\Box$ Class I devices with meas-	ing to former notified body	
762202M	uring function		or
762226M	Class III implantable cus-		
762240M	tom-made-device		□ Evidence that a competent au-
766125M	□ Class I reusable surgical instruments		thority of a Member State had granted acc. MDR, Art.59 (1) or
769294M	monuncino		Art.97 (1)



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
777633M			Evidence #1; CA#
766217M			Evidence #2; CA#
766224M			
766231M			
766248M			
766255M			
766262M			
766279M			
766286M			
777565M			
777589M			
4031881G10-07cHaX2	Class III	⊠ N/A	$\boxtimes$ Certification as follows:
	□ Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-FIX	exempted)	or	
	Class IIb / Class IIb im-		or
Individual article number:	plantable (exempted)	□ Identification of the correspond-	
781913	🖾 Class IIa	ing device under MDD/AIMDD	□ N/A - Device did not require a
781920	□ Class I devices in sterile	Individual Article number:	Notified Body certificate under
781937	condition	In case of transfer identifier accord-	Directives
781944	□ Class I devices with meas-	ing to former notified body	
781951	uring function		or
781968	□ Class III implantable cus-		
781975	tom-made-device		$\Box$ Evidence that a competent au-
781982	□ Class I reusable surgical instruments		thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
			Evidence #1; CA#
			Evidence #2; CA#
4031881G10-07aHaWL	Class III	⊠ N/A	⊠ Certification as follows:
	□ Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-FIX +	exempted)	or	or
	Class IIb / Class IIb im-		
Individual article number:	plantable (exempted)	□ Identification of the correspond-	□ N/A - Device did not require a
762141A	🖾 Class IIa	ing device under MDD/AIMDD	Notified Body certificate under
762165A	□ Class I devices in sterile	Individual Article number:	Directives
762189A	condition	In case of transfer identifier accord-	
762202A	□ Class I devices with meas-	ing to former notified body	or
762226A	uring function		
762240A	Class III implantable cus-		Evidence that a competent au-
766125A	tom-made-device		thority of a Member State had granted acc. MDR, Art.59 (1) or
766217A	□ Class I reusable surgical instruments		Art.97 (1)
766224A	monuments		Evidence #1; CA#
766231A			Evidence #2; CA#
766248A			
766255A			
766262A			
766279A			
766286A			



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
4031881G10-07aIIaWL	Class III	🖾 N/A	Certification as follows:
	Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-FIX MONO	exempted)	or	or
	Class IIb / Class IIb im-		
Individual article number:	plantable (exempted)	$\Box$ Identification of the correspond-	□ N/A - Device did not require a
766378M	⊠ Class IIa	ing device under MDD/AIMDD	Notified Body certificate under Directives
766385M	□ Class I devices in sterile condition	Individual Article number:	Directives
766392M		In case of transfer identifier accord- ing to former notified body	or
766408M	□ Class I devices with meas- uring function	ling to former normed body	01
766415M	□ Class III implantable cus-		Evidence that a commetent ov
766422M	tom-made-device		□ Evidence that a competent au- thority of a Member State had
766439M	□ Class I reusable surgical		granted acc. MDR, Art.59 (1) or
766446M	instruments		Art.97 (1)
777749M			Evidence #1; CA#
777763M			Evidence #2; CA#
766538M			
766545M			
766552M			
766569M			
766576M			
766583M			
766590M			
766606M 777602M			
777626M			
4031881G10-07aHaWL	Class III	⊠ N/A	Certification as follows:
4031001G10-07a11a WL			G1 037875 0044 Rev. 01
KD-FIX MONO +	<ul> <li>□ Class IIb implantable (non-exempted)</li> <li>□ Class IIb / Class IIb im-</li> </ul>	or	or
Individual article number:	plantable (exempted)	□ Identification of the correspond-	□ N/A - Device did not require a
766378A	🖾 Class IIa	ing device under MDD/AIMDD	Notified Body certificate under
766385A	□ Class I devices in sterile	Individual Article number:	Directives
766392A	condition	In case of transfer identifier accord-	
766408A	Class I devices with meas-	ing to former notified body	or
766415A	uring function		
766422A	Class III implantable cus- tom-made-device		Evidence that a competent au-
766439A	□ Class I reusable surgical		thority of a Member State had granted acc. MDR, Art.59 (1) or
766446A	instruments		Art.97 (1)
777749A			Evidence #1; CA#
766538A			Evidence #2; CA#
766545A			
766552A			
766569A			
766576A			
766583A			
766590A			
777602A			
4031881G10-07aHaWL	□ Class III	🖾 N/A	Certification as follows:



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
	Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-FIX SOLO	exempted)	or	or
	□ Class IIb / Class IIb im-		
Individual article number:	plantable (exempted)	□ Identification of the correspond-	□ N/A - Device did not require a
766699	⊠ Class IIa	ing device under MDD/AIMDD	Notified Body certificate under
766705	Class I devices in sterile	Individual Article number:	Directives
766712	condition	In case of transfer identifier accord-	
766729	□ Class I devices with meas- uring function	ing to former notified body	or
766736			
766743	Class III implantable cus- tom-made-device		Evidence that a competent authority of a Member State had
766750	□ Class I reusable surgical		granted acc. MDR, Art.59 (1) or
766767	instruments		Art.97 (1)
777787	_		Evidence #1; CA#
777800			Evidence #2; CA#
766699M			
766705M			
766712M			
766729M			
766736M			
766743M			
766750M			
766767M			
777787M			
777800M			
777381M			
777398M			
777404M			
777428M			
777442M			
777459M			
777466M			
766927M			
777411M			
777435M			
4031881G10-07bHaWT	Class III	× N/A	Certification as follows:
4051001G10-07D11a w 1		A N/A	
VD FIV MONO SAFETV	Class IIb implantable (non- exempted)		G1 037875 0044 Rev. 01
KD-FIX-MONO SAFETY	□ Class IIb / Class IIb im-	or	or
Ter discidente and the state	plantable (exempted)		
Individual article number:	⊠ Class IIa	☐ Identification of the correspond-	□ N/A - Device did not require a
767337		ing device under MDD/AIMDD Individual Article number:	Notified Body certificate under Directives
767344	Class I devices in sterile		
767351	□ Class I devices with meas-	In case of transfer identifier accord- ing to former notified body	or
767368	uring function	ing to former notified body	
767375	□ Class III implantable cus-		$\Box$ Evidence that a competent au-
767382	tom-made-device		thority of a Member State had
767399	□ Class I reusable surgical		granted acc. MDR, Art.59 (1) or
767405	instruments		Art.97 (1)
777886			Evidence #1; CA#



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
777909 767498 767504 767511 767528 767535 767542 767559 777305 777329			Evidence #2; CA#
4031881G10-07bHaWT KD-FIX-MONO SAFETY+ Individual article number: 767337A 767344A 767351A 767368A 767375A 767382A 767399A 777886A 767594A 767504A 767511A 767528A 767535A 767535A 767535A 767559A 777305A	<ul> <li>□ Class III</li> <li>□ Class IIb implantable (non-exempted)</li> <li>□ Class IIb / Class IIb implantable (exempted)</li> <li>⊠ Class IIa</li> <li>□ Class I devices in sterile condition</li> <li>□ Class I devices with measuring function</li> <li>□ Class III implantable custom-made-device</li> <li>□ Class I reusable surgical instruments</li> </ul>	<ul> <li>N/A</li> <li>or</li> <li>☐ Identification of the corresponding device under MDD/AIMDD</li> <li>Individual Article number:</li> <li>In case of transfer identifier according to former notified body</li> </ul>	<ul> <li>Certification as follows:</li> <li>G1 037875 0044 Rev. 01</li> <li>or</li> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> <li>Evidence #2; CA#</li> </ul>
777329A 4031881G10-07bHaWT KD-FIX-MONO SAFETY PRO Individual article number: 767528B 767535B 767542B 767559B 777305B	<ul> <li>Class III</li> <li>Class IIb implantable (non-exempted)</li> <li>Class IIb / Class IIb implantable (exempted)</li> <li>Class IIa</li> <li>Class I devices in sterile condition</li> <li>Class I devices with measuring function</li> <li>Class II implantable custom-made-device</li> <li>Class I reusable surgical instruments</li> </ul>	<ul> <li>☑ N/A</li> <li>or</li> <li>☐ Identification of the corresponding device under MDD/AIMDD</li> <li>Individual Article number:</li> <li>In case of transfer identifier according to former notified body</li> </ul>	<ul> <li>Certification as follows:</li> <li>G1 037875 0044 Rev. 01</li> <li>or</li> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> </ul>



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
4031881G10-07bHaWT	□ Class III	⊠ N/A	$\boxtimes$ Certification as follows:
KD-FIX-SAFETY	□ Class IIb implantable (non- exempted)	or	G1 037875 0044 Rev. 01 or
	Class IIb / Class IIb im-		
Individual article number:	plantable (exempted)	$\Box$ Identification of the correspond-	□ N/A - Device did not require a
767016	⊠ Class IIa	ing device under MDD/AIMDD	Notified Body certificate under Directives
767023	□ Class I devices in sterile condition	Individual Article number:	Directives
767030		In case of transfer identifier accord- ing to former notified body	or
767047	□ Class I devices with meas- uring function	ling to former normed body	01
767054	□ Class III implantable cus-		
767061	tom-made-device		□ Evidence that a competent au- thority of a Member State had
767078	□ Class I reusable surgical		granted acc. MDR, Art.59 (1) or
767085	instruments		Art.97 (1)
769096			Evidence #1; CA#
777862			Evidence #2; CA#
767177			
767184			
767191			
767207			
767214			
767221			
767238			
767245			
769102			
769270			
4031881G10-07bHaWT	Class III	🖾 N/A	Certification as follows:
	□ Class IIb implantable (non-		G1 037875 0044 Rev. 01
	$\Box$ Class no implantable (non-		
KD-FIX-SAFETY +	exempted)	or	or
KD-FIX-SAFETY +	1 1	or	or
KD-FIX-SAFETY + Individual article number:	exempted)		
	exempted)	or Identification of the correspond- ing device under MDD/AIMDD	□ N/A - Device did not require a Notified Body certificate under
Individual article number:	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile	□ Identification of the correspond-	□ N/A - Device did not require a
Individual article number: 767016A	exempted) □ Class IIb / Class IIb im- plantable (exempted) ⊠ Class IIa	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	□ N/A - Device did not require a Notified Body certificate under
Individual article number: 767016A 767023A	exempted) □ Class IIb / Class IIb im- plantable (exempted) ⊠ Class IIa □ Class I devices in sterile condition □ Class I devices with meas-	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number:	□ N/A - Device did not require a Notified Body certificate under
Individual article number: 767016A 767023A 767030A	exempted) □ Class IIb / Class IIb im- plantable (exempted) ⊠ Class IIa □ Class I devices in sterile condition □ Class I devices with meas- uring function	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	□ N/A - Device did not require a Notified Body certificate under Directives
Individual article number: 767016A 767023A 767030A 767047A	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile condition  Class I devices with meas- uring function  Class III implantable cus-	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au-</li> </ul>
Individual article number: 767016A 767023A 767030A 767047A 767054A	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile condition  Class I devices with meas- uring function  Class III implantable cus- tom-made-device	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au- thority of a Member State had</li> </ul>
Individual article number: 767016A 767023A 767030A 767047A 767054A 767061A	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile condition  Class I devices with meas- uring function  Class III implantable cus- tom-made-device  Class I reusable surgical	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au-</li> </ul>
Individual article number: 767016A 767023A 767030A 767047A 767054A 767061A 767078A	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile condition  Class I devices with meas- uring function  Class III implantable cus- tom-made-device	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> </ul>
Individual article number: 767016A 767023A 767030A 767047A 767054A 767061A 767078A 769096A	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile condition  Class I devices with meas- uring function  Class III implantable cus- tom-made-device  Class I reusable surgical	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or</li> </ul>
Individual article number: 767016A 767023A 767030A 767047A 767054A 767054A 767061A 767078A 769096A 767177A	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile condition  Class I devices with meas- uring function  Class III implantable cus- tom-made-device  Class I reusable surgical	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> </ul>
Individual article number: 767016A 767023A 767030A 767047A 767054A 767061A 767078A 769096A 769177A 767184A	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile condition  Class I devices with meas- uring function  Class III implantable cus- tom-made-device  Class I reusable surgical	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> </ul>
Individual article number: 767016A 767023A 767030A 767047A 767054A 767061A 767078A 769096A 767177A 767184A 767191A 767207A	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile condition  Class I devices with meas- uring function  Class III implantable cus- tom-made-device  Class I reusable surgical	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> </ul>
Individual article number: 767016A 767023A 767030A 767047A 767054A 767061A 767078A 769096A 767177A 767184A 767191A 767207A 767214A	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile condition  Class I devices with meas- uring function  Class III implantable cus- tom-made-device  Class I reusable surgical	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> </ul>
Individual article number: 767016A 767023A 767030A 767047A 767054A 767061A 767078A 769096A 767177A 767184A 767191A 767207A 767221A	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile condition  Class I devices with meas- uring function  Class III implantable cus- tom-made-device  Class I reusable surgical	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> </ul>
Individual article number: 767016A 767023A 767030A 767047A 767054A 767061A 767078A 769096A 767177A 767184A 767191A 767207A 767214A	exempted)  Class IIb / Class IIb im- plantable (exempted)  Class IIa  Class I devices in sterile condition  Class I devices with meas- uring function  Class III implantable cus- tom-made-device  Class I reusable surgical	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> </ul>



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
4031881G10-07bHaWT	Class III	🖾 N/A	Certification as follows:
	□ Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-FIX-SAFETY PRO	exempted)	or	or
	Class IIb / Class IIb im-		
Individual article number:	plantable (exempted) ⊠ Class IIa	□ Identification of the correspond-	$\square$ N/A - Device did not require a
767207B	$\Box$ Class I devices in sterile	ing device under MDD/AIMDD	Notified Body certificate under Directives
767214B	condition	Individual Article number: In case of transfer identifier accord-	
767221B 767238B	□ Class I devices with meas-	ing to former notified body	or
769102B	uring function		
/09102B	□ Class III implantable cus- tom-made-device		□ Evidence that a competent au- thority of a Member State had
	□ Class I reusable surgical instruments		granted acc. MDR, Art.59 (1) or Art.97 (1)
			Evidence #1; CA#
			Evidence #2; CA#
4031881G10-07bHaWT	Class III	⊠ N/A	Certification as follows:
	□ Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-FIX-SOLO SAFETY	exempted)	or	or
* * * * * * * *	□ Class IIb / Class IIb im- plantable (exempted)		_
Individual article number:	⊠ Class IIa	☐ Identification of the correspond- ing device under MDD/AIMDD	□ N/A - Device did not require a Notified Body certificate under
777961 777978	$\Box$ Class I devices in sterile	Individual Article number:	Directives
777985	condition	In case of transfer identifier accord-	
778005	□ Class I devices with meas-	ing to former notified body	or
778029	uring function		
778036	□ Class III implantable cus-		$\Box$ Evidence that a competent au-
778043	tom-made-device		thority of a Member State had granted acc. MDR, Art.59 (1) or
778050	Class I reusable surgical		Art.97 (1)
777992	monto		Evidence #1; CA#
778012			Evidence #2; CA#
4031881G10-09IIaM3	Class III	⊠ N/A	Certification as follows:
	Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-FLEX	exempted)	or	or
	Class IIb / Class IIb im-		
Individual article number:	plantable (exempted) ⊠ Class IIa	☐ Identification of the correspond-	□ N/A - Device did not require a
773468M		ing device under MDD/AIMDD	Notified Body certificate under Directives
773475M	□ Class I devices in sterile condition	Individual Article number: In case of transfer identifier accord-	
773482M 773499M	□ Class I devices with meas-	ing to former notified body	or
773505M	uring function	- *	
773512M	□ Class III implantable cus-		□ Evidence that a competent au-
769171M	tom-made-device		thority of a Member State had
773468	Class I reusable surgical		granted acc. MDR, Art.59 (1) or Art.97 (1)
773475	instruments		Evidence #1; CA#
773482			Evidence #2; CA#
773499			
773505			
773512			



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
769171			
4031881G10-09IIaM3	□ Class III	⊠ N/A	$\boxtimes$ Certification as follows:
KD-FLEX PLUS	Class IIb implantable (non-exempted)	or	G1 037875 0044 Rev. 01 or
Individual article number: 773741	<ul> <li>□ Class IIb / Class IIb implantable (exempted)</li> <li>☑ Class IIa</li> <li>□ Class I devices in sterile condition</li> <li>□ Class I devices with measuring function</li> <li>□ Class III implantable custom-made-device</li> <li>□ Class I reusable surgical instruments</li> </ul>	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord- ing to former notified body	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> <li>Evidence #2; CA#</li> </ul>
4031881G10-06aHaW9	Class III	🖾 N/A	Certification as follows:
KD-FLEXOLINE	□ Class III □ Class IIb implantable (non- exempted) □ Class IIb / Class IIb im-	or	G1 037875 0044 Rev. 01 or
Individual article number:	plantable (exempted)		
771280D	$\boxtimes$ Class IIa	☐ Identification of the correspond- ing device under MDD/AIMDD	□ N/A - Device did not require a Notified Body certificate under
771303D	□ Class I devices in sterile	Individual Article number:	Directives
771204D	condition	In case of transfer identifier accord-	
771327D	□ Class I devices with meas-	ing to former notified body	or
771228D	uring function		
771242D	□ Class III implantable cus-		□ Evidence that a competent au-
771341D	tom-made-device		thority of a Member State had
771624D	Class I reusable surgical		granted acc. MDR, Art.59 (1) or Art.97 (1)
771266D	instruments		Evidence #1; CA#
771365D			Evidence #1; CA#
771389D			Evidence #2, CA#
4031881G10-03aHaV8	Class III		Certification as follows:
4051001010-054114 0		⊠ N/A	
KD-FLY	□ Class IIb implantable (non- exempted) □ Class IIb / Class IIb im-	or	G1 037875 0044 Rev. 01 or
Individual article number:	plantable (exempted)		
741801D	$\boxtimes$ Class IIa	☐ Identification of the correspond- ing device under MDD/AIMDD	□ N/A - Device did not require a Notified Body certificate under
741900D	$\Box$ Class I devices in sterile	Individual Article number:	Directives
741900D 742006D	condition	In case of transfer identifier accord-	
742000D 742105D	□ Class I devices with meas-	ing to former notified body	or
742105D 742204D	uring function		
742204D 742303D	□ Class III implantable cus-		Evidence that a competent au-
742303D 742402D	tom-made-device		thority of a Member State had
	□ Class I reusable surgical		granted acc. MDR, Art.59 (1) or
742501D 742525D	instruments		Art.97 (1)
742525D			Evidence #1; CA# Evidence #2; CA#
742549D			



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
742600D			
742709D			
742723D			
742747D			
742761D			
741801			
741900			
742006			
742105			
742204			
742303			
742402			
742501			
742525			
742549			
742563			
742600			
742709			
742723			
742747			
742761			
4031881G10-03bHaVF	Class III	🖾 N/A	Certification as follows:
4051001010-050114 11			G1 037875 0044 Rev. 01
KD-FLY SAFETY	□ Class IIb implantable (non- exempted)		
KD-FET SAFETT	□ Class IIb / Class IIb im-	or	or
Individual article number:	plantable (exempted)		
917947	⊠ Class IIa	☐ Identification of the correspond- ing device under MDD/AIMDD	□ N/A - Device did not require a Notified Body certificate under
917954	□ Class I devices in sterile	Individual Article number:	Directives
917961	condition	In case of transfer identifier accord-	
917978	$\Box$ Class I devices with meas-	ing to former notified body	or
917978	uring function		
917985	Class III implantable cus-		$\Box$ Evidence that a competent au-
	tom-made-device		thority of a Member State had
918005 918012	□ Class I reusable surgical		granted acc. MDR, Art.59 (1) or $A \neq 07$ (1)
	instruments		Art.97 (1)
918029 018036			Evidence #1; CA#
918036			Evidence #2; CA#
918043			
918050			
918067			
918074			
918081			
918098			
919903			
919910			
914175			
914182			
917947D			
917954D			



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
917961D			
917978D			
917985D			
917992D			
918005D			
918012D			
918029D			
918036D			
918043D			
918050D			
918067D			
918074D			
918081D			
918098D			
919903D			
919910D			
914175D			
914182D			
4031881G10-04bHaVS	Class III	🖾 N/A	Certification as follows:
	□ Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-JECT	exempted)	or	or
	Class IIb / Class IIb im-	01	01
Individual article number:	plantable (exempted)		
802229	⊠ Class IIa	☐ Identification of the correspond- ing device under MDD/AIMDD	□ N/A - Device did not require a Notified Body certificate under
802236	□ Class I devices in sterile	Individual Article number:	Directives
805220	condition	In case of transfer identifier accord-	
805220	□ Class I devices with meas-	ing to former notified body	or
805244	uring function		
	□ Class III implantable cus-		Evidence that a competent au-
810224	tom-made-device		thority of a Member State had
820223	□ Class I reusable surgical		granted acc. MDR, Art.59 (1) or
872475	instruments		Art.97 (1)
802229B			Evidence #1; CA#
805220C			Evidence #2; CA#
805244B			
810224C			
871683C			
4031881G10-04fIIaWN	□ Class III	⊠ N/A	$\boxtimes$ Certification as follows:
	Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-JECT	exempted)	or	or
	Class IIb / Class IIb im-		
Individual article number:	plantable (exempted)	$\Box$ Identification of the correspond-	□ N/A - Device did not require a
802236K	⊠ Class IIa	ing device under MDD/AIMDD	Notified Body certificate under
802229K	Class I devices in sterile	Individual Article number:	Directives
805220K	condition	In case of transfer identifier accord-	
805237K	Class I devices with meas-	ing to former notified body	or
805244K	uring function		
810224K	□ Class III implantable cus- tom-made-device		$\Box$ Evidence that a competent au-
820223K	tom-made-device		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 Refer- ence(s) of the devices under MDR application, and the NB Identification
	Class I reusable surgical		granted acc. MDR, Art.59 (1) or Art.97 (1)
	instruments		Evidence #1; CA#
			Evidence #2; CA#
4031881G10-04aIIaVK	Class III	⊠ N/A	Certification as follows:
	□ Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-JECT III	exempted)	or	or
	□ Class IIb / Class IIb im-		
Individual article number:	plantable (exempted)	□ Identification of the correspond-	□ N/A - Device did not require a
802342	🖾 Class IIa	ing device under MDD/AIMDD	Notified Body certificate under
802441	□ Class I devices in sterile	Individual Article number:	Directives
803349	condition	In case of transfer identifier accord-	
803448	Class I devices with meas-	ing to former notified body	or
805343	uring function		
805350	Class III implantable cus- tom-made-device		Evidence that a competent au- thority of a Member State had
805367	□ Class I reusable surgical		granted acc. MDR, Art.59 (1) or
805442	instruments		Art.97 (1)
805459			Evidence #1; CA#
805466			Evidence #2; CA#
810347			
810361			
810446			
820025			
820346			
820445			
820667			
821343			
822647			
831342			
831359			
831366			
831786			
831793			
870464			
870471			
870709			
871263			
871379 872536			
872536 873151			
873168			
875483			
875485 4031881G10-04cHaVZ	Class III	🛛 🖾 N/A	Contification of fall-
TUJ1001010-04011aVL			Certification as follows:
KD-JECT III	Class IIb implantable (non- exempted)		G1 037875 0044 Rev. 01
ND-9ECT III	□ Class IIb / Class IIb im-	or	or
Individual article number:	plantable (exempted)		
802441R	⊠ Class IIa	☐ Identification of the correspond- ing device under MDD/AIMDD	□ N/A - Device did not require a Notified Body certificate under
0027711		Individual Article number:	Directives



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
803448R 805442R 805459R 805466R 810446R	<ul> <li>Class I devices in sterile condition</li> <li>Class I devices with meas- uring function</li> <li>Class III implantable cus- tom-made-device</li> </ul>	In case of transfer identifier accord- ing to former notified body	or Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or
820445R 4031881G10-04eIIaWF	□ Class I reusable surgical instruments		Art.97 (1) Evidence #1; CA# Evidence #2; CA#
KD-JECT III	<ul> <li>Class III</li> <li>Class IIb implantable (non-exempted)</li> <li>Class IIb / Class IIb im-</li> </ul>	⊠ N/A or	<ul> <li>Certification as follows:</li> <li>G1 037875 0044 Rev. 01</li> <li>or</li> </ul>
Individual article number: 802359 803356 805374 805381 805398	plantable (exempted) ⊠ Class IIa □ Class I devices in sterile condition □ Class I devices with meas- uring function □ Class II devices with meas-	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord- ing to former notified body	<ul> <li>□ N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> </ul>
810354 820353 865637 871737 873281	Class III implantable cus- tom-made-device  Class I reusable surgical instruments		□ Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4031881G10-05aHaVW KD-JECT III Individual article number: 870082 870105 870129	<ul> <li>Class III</li> <li>Class IIb implantable (non-exempted)</li> <li>Class IIb / Class IIb implantable (exempted)</li> <li>Class IIa</li> <li>Class I devices in sterile condition</li> <li>Class I devices with meas-</li> </ul>	<ul> <li>☑ N/A</li> <li>or</li> <li>□ Identification of the corresponding device under MDD/AIMDD</li> <li>Individual Article number:</li> <li>In case of transfer identifier according to former notified body</li> </ul>	<ul> <li>Certification as follows:</li> <li>G1 037875 0044 Rev. 01</li> <li>or</li> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> </ul>
870143 870167 870181 870198 870204 870303 870334 870365	<ul> <li>Class I devices with measuring function</li> <li>Class III implantable custom-made-device</li> <li>Class I reusable surgical instruments</li> </ul>	ing to former notified body	<ul> <li>Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> <li>Evidence #2; CA#</li> </ul>
870396 870501 870518 870525 870532 870532 870549 870747 873267			
8/326/ 4031881G10-05bHaW5	Class III	⊠ N/A	Certification as follows:



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
	Class IIb implantable (non-		G1 037875 0044 Rev. 01
KD-JECT III	exempted)	or	or
Individual article number: 801345 811344 831373	<ul> <li>□ Class IIb / Class IIb implantable (exempted)</li> <li>⊠ Class IIa</li> <li>□ Class I devices in sterile condition</li> </ul>	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord-	□ N/A - Device did not require a Notified Body certificate under Directives
831380	□ Class I devices with meas-	ing to former notified body	or
831397	uring function		
831700	□ Class III implantable cus-		$\Box$ Evidence that a competent au-
831724	tom-made-device		thority of a Member State had
831755	$\Box$ Class I reusable surgical		granted acc. MDR, Art.59 (1) or Art.97 (1)
831762	instruments		Evidence #1; CA#
831702			Evidence #2; CA#
870600			
4031881G10-06aIIaW9	Class III	⊠ N/A	Certification as follows:
4031001G10-00a11a w 9			G1 037875 0044 Rev. 01
KD-LINE	Class IIb implantable (non- exempted)		
KD-LINE	□ Class IIb / Class IIb im-	or	or
T., J., .: J.,	plantable (exempted)		
Individual article number:	⊠ Class IIa	☐ Identification of the correspond- ing device under MDD/AIMDD	□ N/A - Device did not require a Notified Body certificate under
770283D	$\Box$ Class I devices in sterile	Individual Article number:	Directives
770306D	condition	In case of transfer identifier accord-	
770207D	□ Class I devices with meas-	ing to former notified body	or
770320D 772256D	uring function		
	□ Class III implantable cus-		□ Evidence that a competent au-
770221D 770245D	tom-made-device		thority of a Member State had
770245D 770344D	□ Class I reusable surgical		granted acc. MDR, Art.59 (1) or
770627D	instruments		Art.97 (1)
770269D			Evidence #1; CA#
770368D			Evidence #2; CA#
770382D			
772263D			
770283F			
770306F			
770207F			
770320F			
772256F			
770221F			
770245F			
770344F			
770627F			
770269F			
770368F			
770382F			
772263F			
4031881G10-06bIIaWG	□ Class III	⊠ N/A	<ul> <li>Certification as follows:</li> <li>G1 037875 0044 Rev. 01</li> </ul>



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
KD-LINE	Class IIb implantable (non-exempted)	or	or
Individual article number: 770849D 770863D 770825D 770764D 773406D 770641D 770788D 770887D	<ul> <li>Class IIb / Class IIb implantable (exempted)</li> <li>⊠ Class IIa</li> <li>□ Class I devices in sterile condition</li> <li>□ Class I devices with measuring function</li> <li>□ Class III implantable custom-made-device</li> <li>□ Class I reusable surgical</li> </ul>	<ul> <li>Identification of the correspond- ing device under MDD/AIMDD</li> <li>Individual Article number:</li> <li>In case of transfer identifier accord- ing to former notified body</li> </ul>	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> </ul>
776018A	instruments		Evidence #1; CA#
776025A			Evidence #2; CA#
776032A			
4031881G10-04aIIaVK KDM syringes	□ Class III □ Class IIb implantable (non- exempted)	⊠ N/A or	<ul> <li>☑ Certification as follows:</li> <li>G1 037875 0044 Rev. 01</li> <li>or</li> </ul>
Individual article number: 821107 906132 906149 906156 906163 906170 906187 906194 906200 906217 906224 906330 906347 906736 906736 906743 906750 906750 906767 906958 908037 908051 908051 908051 908068 908075 908136 908150	<ul> <li>□ Class IIb / Class IIb implantable (exempted)</li> <li>□ Class I devices in sterile condition</li> <li>□ Class I devices with measuring function</li> <li>□ Class II devices with measuring function</li> <li>□ Class III implantable custom-made-device</li> <li>□ Class I reusable surgical instruments</li> </ul>	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord- ing to former notified body	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> <li>□ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> <li>Evidence #2; CA#</li> </ul>
4031881G10-04dIIaW8 KDM syringes	<ul> <li>Class III</li> <li>Class IIb implantable (non-exempted)</li> <li>Class IIb / Class IIb im-</li> </ul>	⊠ N/A or	<ul> <li>Certification as follows:</li> <li>G1 037875 0044 Rev. 01</li> <li>or</li> </ul>
Individual article number:	plantable (exempted)		



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
906316	<ul> <li>☑ Class IIa</li> <li>□ Class I devices in sterile condition</li> </ul>	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number:	□ N/A - Device did not require a Notified Body certificate under Directives
	□ Class I devices with meas- uring function	In case of transfer identifier accord- ing to former notified body	or
	<ul> <li>□ Class III implantable custom-made-device</li> <li>□ Class I reusable surgical</li> </ul>		□ Evidence that a competent au- thority of a Member State had
	instruments		granted acc. MDR, Art.59 (1) or Art.97 (1)
			Evidence #1; CA# Evidence #2; CA#
4031881G10-05aHaVW	Class III	X N/A	Certification as follows:
	□ Class IIb implantable (non-		G1 037875 0044 Rev. 01
KDM syringes	exempted)	or	or
Individual article number:	□ Class IIb / Class IIb im- plantable (exempted)		
906255	⊠ Class IIa	☐ Identification of the correspond- ing device under MDD/AIMDD	□ N/A - Device did not require a Notified Body certificate under
906255	□ Class I devices in sterile	Individual Article number:	Directives
906286	condition	In case of transfer identifier accord-	
906293	□ Class I devices with meas- uring function	ing to former notified body	or
906309	Class III implantable cus- tom-made-device		□ Evidence that a competent au- thority of a Member State had
	□ Class I reusable surgical		granted acc. MDR, Art.59 (1) or Art.97 (1)
			Evidence #1; CA#
			Evidence #2; CA#
4031881G10-05bIIaW5	□ Class III	⊠ N/A	$\boxtimes$ Certification as follows:
VDM auringaa	Class IIb implantable (non- exempted)		G1 037875 0044 Rev. 01
KDM syringes	□ Class IIb / Class IIb im-	or	or
Individual article number:	plantable (exempted)	☐ Identification of the correspond-	□ N/A - Device did not require a
906248	⊠ Class IIa	ing device under MDD/AIMDD	Notified Body certificate under
906774	□ Class I devices in sterile	Individual Article number:	Directives
906972	condition	In case of transfer identifier accord- ing to former notified body	0.5
906996	□ Class I devices with meas- uring function	ing to former notified body	or
908112 908174	Class III implantable cus- tom-made-device		□ Evidence that a competent au- thority of a Member State had
	□ Class I reusable surgical instruments		granted acc. MDR, Art.59 (1) or Art.97 (1)
			Evidence #1; CA#
			Evidence #2; CA#
4031881G10-11IIaKN		⊠ N/A	Certification as follows:
KDM transfusion sets	Class IIb implantable (non- exempted)	or	G1 037875 0044 Rev. 01
	Class IIb / Class IIb im-		or
Individual article number:	plantable (exempted)	☐ Identification of the correspond-	$\square$ N/A - Device did not require a
525524D	⊠ Class IIa	ing device under MDD/AIMDD	Notified Body certificate under Directives
525203D		Individual Article number:	Directives



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
	<ul> <li>Class I devices in sterile condition</li> <li>Class I devices with meas-</li> </ul>	In case of transfer identifier accord- ing to former notified body	or
	<ul> <li>Class I devices with measuring function</li> <li>Class III implantable custom-made-device</li> <li>Class I reusable surgical instruments</li> </ul>		<ul> <li>Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> <li>Evidence #2: CA#</li> </ul>
4031881G10-10IIaKF	Class III	× N/A	$\boxtimes$ Certification as follows:
KD-OBT	□ Class IIb implantable (non-exempted)	or	G1 037875 0044 Rev. 01 or
Individual article number: 768952 768969 768976 768983	<ul> <li>□ Class IIb / Class IIb implantable (exempted)</li> <li>⊠ Class IIa</li> <li>□ Class I devices in sterile condition</li> <li>□ Class I devices with meas-</li> </ul>	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord- ing to former notified body	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> </ul>
768990 769003 768952M 768969M 768976M 768983M	uring function  Class III implantable cus- tom-made-device  Class I reusable surgical instruments		□ Evidence that a competent au- thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
768990M 769003M			
4031881G10-02bHaV4	Class III	🖾 N/A	Certification as follows:
KD-PENOFINE	Class IIb implantable (non- exempted)	or	G1 037875 0044 Rev. 01 or
Individual article number: 919965 919972 920183 920190	<ul> <li>□ Class IIb / Class IIb implantable (exempted)</li> <li>⊠ Class IIa</li> <li>□ Class I devices in sterile condition</li> <li>□ Class I devices with measuring function</li> </ul>	☐ Identification of the correspond- ing device under MDD/AIMDD Individual Article number: In case of transfer identifier accord- ing to former notified body	<ul> <li>N/A - Device did not require a Notified Body certificate under Directives</li> <li>or</li> </ul>
919996 920008 920015 920220 920022 920039	Class III implantable cus- tom-made-device Class I reusable surgical instruments		<ul> <li>Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</li> <li>Evidence #1; CA#</li> <li>Evidence #2; CA#</li> </ul>
920039			Evidence #2; CA#
4031881G10-02aHaUV	□ Class III	× N/A	Certification as follows:
KD-PENOFINE	□ Class IIb implantable (non- exempted) □ Class IIb / Class IIb im-	or	G1 037875 0044 Rev. 01 or
Individual article number: 904206	plantable (exempted) ⊠ Class IIa	☐ Identification of the correspond- ing device under MDD/AIMDD	□ N/A - Device did not require a Notified Body certificate under



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 Refer- ence(s) of the devices under MDR application, and the NB Identification
904220	□ Class I devices in sterile	In case of transfer identifier accord-	
904237	condition	ing to former notified body	or
907009	□ Class I devices with meas-		
907016	uring function		□ Evidence that a competent au-
907023	Class III implantable cus-		thority of a Member State had
907030	tom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1)
904244	□ Class I reusable surgical instruments		Evidence #1; CA#
904251	Instruments		Evidence #2; CA#
908303			
904268			
904275			
904282			
910719			
914014			
914021			
910733			
904206T			
904213T			
904220T			
904237T			
907009T			
907016T			
907023T			
907030T			
904244T			
904251T			
908303T			
904268T			
904275T			
904282T			
910719T			
916124T			
914014T			
914021T			
910733T			
910/551			



## 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 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 Refer- ence(s) of the devices under 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 inter- nal reference traceable to each version of the letter	Action
2024-04-11	713330445_CL	Initial issue