

**Add value.
Inspire trust.**

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@tuvsud.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.

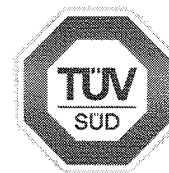
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Trade Register Munich HRB 85 742
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VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

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

TÜV SÜD Product Service GmbH
Ridlerstr. 65
80339 Munich
Germany

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Hotline: +49 89 50084-747

TUV®



- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.
If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (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 www.tuvsud.com/ps-cert?q=cert:CL 037875 0054 Rev. 00

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

TÜV SÜD Product Service GmbH
Medical and Health Services


Katarzyna Dziadosz [11. April 2024 13:53 GMT+2]

Katarzyna Dziadosz
Conformity Assessment Responsible (CARE)



Claus Matthias Mumme
Application Reviewer

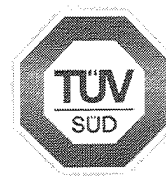


Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR 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
4031881G10-08bIIaX6 KD-DRIP Individual article number: 430224 430231 430255 430262 430279 430286 430293	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-08IIaLU KD-DRIP Individual article number: 430415 430422 430200 430446	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-07aIIaWL KD-FIX Individual article number: 762141M 762165M 762172M 762189M 762202M 762226M 762240M 766125M 769294M	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



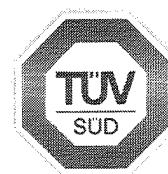
Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
777633M 766217M 766224M 766231M 766248M 766255M 766262M 766279M 766286M 777565M 777589M			Evidence #1; CA# Evidence #2; CA#
4031881G10-07cIIaX2 KD-FIX Individual article number: 781913 781920 781937 781944 781951 781968 781975 781982	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-07aIIaWL KD-FIX + Individual article number: 762141A 762165A 762189A 762202A 762226A 762240A 766125A 766217A 766224A 766231A 766248A 766255A 766262A 766279A 766286A 777565A	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#



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4031881G10-07aIIaWL KD-FIX MONO Individual article number: 766378M 766385M 766392M 766408M 766415M 766422M 766439M 766446M 777749M 777763M 766538M 766545M 766552M 766569M 766576M 766583M 766590M 766606M 777602M 777626M	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-07aIIaWL KD-FIX MONO + Individual article number: 766378A 766385A 766392A 766408A 766415A 766422A 766439A 766446A 777749A 766538A 766545A 766552A 766569A 766576A 766583A 766590A 777602A	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-07aIIaWL	<input type="checkbox"/> Class III	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows:



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KD-FIX SOLO Individual article number: 766699 766705 766712 766729 766736 766743 766750 766767 777787 777800 766699M 766705M 766712M 766729M 766736M 766743M 766750M 766767M 777787M 777800M 777381M 777398M 777404M 777428M 777442M 777459M 777466M 766927M 777411M 777435M	<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 type="checkbox"/> Class I reusable surgical instruments	or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-07bIIaWT KD-FIX-MONO SAFETY Individual article number: 767337 767344 767351 767368 767375 767382 767399 767405 777886	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



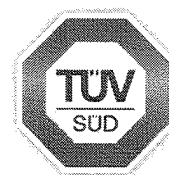
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777909 767498 767504 767511 767528 767535 767542 767559 777305 777329			Evidence #2; CA#
4031881G10-07bIIaWT KD-FIX-MONO SAFETY+ Individual article number: 767337A 767344A 767351A 767368A 767375A 767382A 767399A 777886A 767498A 767504A 767511A 767528A 767535A 767542A 767559A 777305A 777329A	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-07bIIaWT KD-FIX-MONO SAFETY PRO Individual article number: 767528B 767535B 767542B 767559B 777305B	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



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4031881G10-07bIIaWT KD-FIX-SAFETY Individual article number: 767016 767023 767030 767047 767054 767061 767078 767085 769096 777862 767177 767184 767191 767207 767214 767221 767238 767245 769102 769270	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	Evidence #2; CA# <input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-07bIIaWT KD-FIX-SAFETY + Individual article number: 767016A 767023A 767030A 767047A 767054A 767061A 767078A 769096A 767177A 767184A 767191A 767207A 767214A 767221A 767238A 769102A 769270A	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#



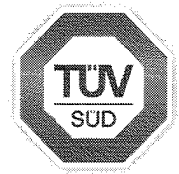
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4031881G10-07bIIaWT KD-FIX-SAFETY PRO Individual article number: 767207B 767214B 767221B 767238B 769102B	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb 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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-07bIIaWT KD-FIX-SOLO SAFETY Individual article number: 777961 777978 777985 778005 778029 778036 778043 778050 777992 778012	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-09IIaM3 KD-FLEX Individual article number: 773468M 773475M 773482M 773499M 773505M 773512M 769171M 773468 773475 773482 773499 773505 773512	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#



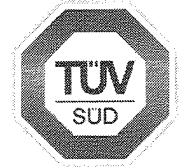
Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
769171 4031881G10-09IIaM3 KD-FLEX PLUS Individual article number: 773741	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-06aIIaW9 KD-FLEXOLINE Individual article number: 771280D 771303D 771204D 771327D 771228D 771242D 771341D 771624D 771266D 771365D 771389D	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-03aIIaV8 KD-FLY Individual article number: 741801D 741900D 742006D 742105D 742204D 742303D 742402D 742501D 742525D 742549D 742563D	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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 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
742600D 742709D 742723D 742747D 742761D 741801 741900 742006 742105 742204 742303 742402 742501 742525 742549 742563 742600 742709 742723 742747 742761			
4031881G10-03bIIaVF KD-FLY SAFETY Individual article number: 917947 917954 917961 917978 917985 917992 918005 918012 918029 918036 918043 918050 918067 918074 918081 918098 919903 919910 914175 914182 917947D 917954D	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#



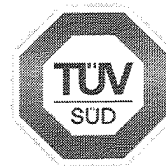
Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
917961D 917978D 917985D 917992D 918005D 918012D 918029D 918036D 918043D 918050D 918067D 918074D 918081D 918098D 919903D 919910D 914175D 914182D			
4031881G10-04bIIaVS KD-JECT Individual article number: 802229 802236 805220 805237 805244 810224 820223 872475 802229B 805220C 805244B 810224C 871683C	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-04fIIaWN KD-JECT Individual article number: 802236K 802229K 805220K 805237K 805244K 810224K 820223K	<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: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had



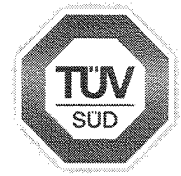
Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I reusable surgical instruments		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4031881G10-04aIIaVK KD-JECT III Individual article number: 802342 802441 803349 803448 805343 805350 805367 805442 805459 805466 810347 810361 810446 820025 820346 820445 820667 821343 822647 831342 831359 831366 831786 831793 870464 870471 870709 871263 871379 872536 873151 873168 875483	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-04cIIaVZ KD-JECT III Individual article number: 802441R	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives



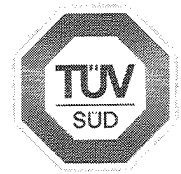
Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
803448R 805442R 805459R 805466R 810446R 820445R	<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 type="checkbox"/> Class I reusable surgical instruments	In case of transfer identifier according to former notified body	or <input type="checkbox"/> 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#
4031881G10-04eIIaWF KD-JECT III Individual article number: 802359 803356 805374 805381 805398 810354 820353 865637 871737 873281	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives <input type="checkbox"/> 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#
4031881G10-05aIIaVW KD-JECT III Individual article number: 870082 870105 870129 870143 870167 870181 870198 870204 870303 870334 870365 870396 870501 870518 870525 870532 870549 870747 873267	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives <input type="checkbox"/> 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#
4031881G10-05bIIaW5	<input type="checkbox"/> Class III	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
KD-JECT III Individual article number: 801345 811344 831373 831380 831397 831700 831724 831755 831762 831779 870600	<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 type="checkbox"/> Class I reusable surgical instruments	or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-06aIIaW9 KD-LINE Individual article number: 770283D 770306D 770207D 770320D 772256D 770221D 770245D 770344D 770627D 770269D 770368D 770382D 772263D 770283F 770306F 770207F 770320F 772256F 770221F 770245F 770344F 770627F 770269F 770368F 770382F 772263F	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-06bIIaWG	<input type="checkbox"/> Class III	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01



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
KD-LINE Individual article number: 770849D 770863D 770825D 770764D 773406D 770641D 770788D 770887D 776018A 776025A 776032A	<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 type="checkbox"/> Class I reusable surgical instruments	or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-04aIIaVK KDM syringes Individual article number: 821107 906132 906149 906156 906163 906170 906187 906194 906200 906217 906224 906330 906347 906736 906743 906750 906767 906958 908037 908051 908068 908075 908136 908150	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-04dIIaW8 KDM syringes Individual article number:	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A or	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or



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
906316	<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 type="checkbox"/> Class I reusable surgical instruments	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-05aIIaVW KDM syringes Individual article number: 906255 906262 906286 906293 906309	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-05bIIaW5 KDM syringes Individual article number: 906248 906774 906972 906996 908112 908174	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-11IIaKN KDM transfusion sets Individual article number: 525524D 525203D	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device <input type="checkbox"/> Class I reusable surgical instruments	In case of transfer identifier according to former notified body	or <input type="checkbox"/> 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#
4031881G10-10IaKF KD-OBT Individual article number: 768952 768969 768976 768983 768990 769003 768952M 768969M 768976M 768983M 768990M 769003M	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-02bIIaV4 KD-PENOFINE Individual article number: 919965 919972 920183 920190 919996 920008 920015 920220 920022 920039 920046	<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 type="checkbox"/> Class I reusable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: In case of transfer identifier according to former notified body	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> 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#
4031881G10-02aIIaUV KD-PENOFINE Individual article number: 904206 904213	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 037875 0044 Rev. 01 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives



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
904220	<input type="checkbox"/> Class I devices in sterile condition	In case of transfer identifier according to former notified body	or
904237	<input type="checkbox"/> Class I devices with measuring function		<input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
907009	<input type="checkbox"/> Class III implantable custom-made-device		Evidence #1; CA#
907016	<input type="checkbox"/> Class I reusable surgical instruments		Evidence #2; CA#
907023			
907030			
904244			
904251			
908303			
904268			
904275			
904282			
910719			
914014			
914021			
910733			
904206T			
904213T			
904220T			
904237T			
907009T			
907016T			
907023T			
907030T			
904244T			
904251T			
908303T			
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904275T			
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910719T			
916124T			
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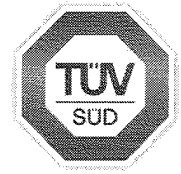


Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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 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
2024-04-11	713330445_CL	Initial issue

