



Product Service

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TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

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National Technology Park
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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
33038	713212698 Ruairi McCaul	+353 (0) 860 755843 ruairi.mccaul@tuvsud.com	-	2024-01-26	1 of 24

TÜV SÜD Product Service GmbH Confirmation Letter

CL 033038 0059 Rev. 00

Reference: 713212698 | 713233811 | 713254205 | 713255917 | 713260952 | 713222487 |
713222510 | 713228654 | 713252400 | 713258121 | 713260959 | 713260960 |
713260963 | 713261373 | 713270171 | 713270207

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: IE-MF-000001530

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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- 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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_033038_0059_Rev.00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-01-26

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services

Ruairi McCaul
Conformity Assessment Responsible (CARE)



Franziska Eckert
Application Reviewer



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

Device name or Basic UDI-DI (under MDR 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
BUDI-DI: 0827002CIRL202007067008E6 Article Numbers: RMS-060012-R RMS-060014-R RMS-060016-R RMS-060018-R RMS-060020-R RMS-060022-R RMS-060024-R RMS-060026-R RMS-060028-R RMS-060030-R	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: 0827002CIRL202007008009CD Article Numbers: USI-500 USI-500-B USI-500-B-T USI-500-LP USI-500-R USI-500-RPC USI-512 USI-512-CE USI-512-LP USI-512-RPC USI-514 USI-514-RPC USI-516 USI-516-LP USI-518 USI-520 USI-520-B USI-520-LP USI-520-R USI-520-RPC USI-522 USI-522-B USI-522-CE USI-522-LP USI-522-R USI-522-RPC USI-524 USI-524-B USI-524-CE USI-524-LP USI-524-R USI-524-RPC USI-526 USI-526-B USI-526-CE USI-526-CE-B USI-526-CE-LP USI-526-CE-R USI-526-LP USI-526-R USI-526-RPC USI-526-RPC-LP	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) 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
USI-528 USI-528-B USI-528-CE USI-528-CE-B USI-528-LP USI-528-R USI-528-RPC USI-530 USI-530-B USI-530-LP USI-530-R USI-530-RPC USI-600 USI-600-B USI-600-B-T USI-600-CE USI-600-LP USI-600-R USI-600-RPC USI-600-RPC-T USI-600-R-T USI-600-T USI-612 USI-614 USI-614-RPC-T USI-616 USI-616-RPC USI-618 USI-620 USI-620-B USI-620-LP USI-620-R USI-620-RPC USI-622 USI-622-B USI-622-CE USI-622-LP USI-622-R USI-622-RPC USI-622-RPC-LP USI-624 USI-624-B USI-624-CE USI-624-CE-LP USI-624-CE-R USI-624-LP USI-624-R USI-624-RPC USI-624-RPC-LP USI-624-RPC-T USI-624-R-T USI-624-T USI-626 USI-626-B USI-626-CE USI-626-CE-B USI-626-CE-LP USI-626-CE-R USI-626-CE-RPC-T USI-626-LP USI-626-R USI-626-RPC USI-626-RPC-LP USI-626-RPC-T USI-626-R-T USI-626-T USI-628 USI-628-B USI-628-CE USI-628-CE-B USI-628-CE-LP USI-628-LP			



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
USI-628-LP-PD USI-628-R USI-628-RPC USI-628-RPC-LP USI-628-RPC-T USI-628-R-T USI-628-T USI-630 USI-630-B USI-630-LP USI-630-R USI-630-RPC USI-700 USI-700-B USI-700-LP USI-700-R USI-700-RPC USI-700-RPC-T USI-700-R-T USI-712 USI-714 USI-716 USI-716-B USI-718 USI-718-P USI-720 USI-720-B USI-720-LP USI-720-R USI-720-RPC USI-722 USI-722-B USI-722-CE USI-722-LP USI-722-P USI-722-R USI-722-RPC USI-724 USI-724-B USI-724-CE USI-724-LP USI-724-P USI-724-R USI-724-RPC USI-724-RPC-LP USI-724-RPC-T USI-724-R-T USI-726 USI-726-B USI-726-CE USI-726-CE-B USI-726-CE-LP USI-726-LP USI-726-P USI-726-R USI-726-RPC USI-726-RPC-LP USI-726-RPC-T USI-726-R-T USI-728 USI-728-B USI-728-CE USI-728-CE-B USI-728-CE-LP USI-728-LP USI-728-LP-PD USI-728-P USI-728-R USI-728-RPC USI-728-RPC-LP USI-728-RPC-T USI-728-R-T			



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
USI-728-T USI-730 USI-730-B USI-730-LP USI-730-R USI-730-RPC USI-800 USI-800-B USI-800-R USI-800-R-P USI-800-RPC USI-822 USI-822-B USI-822-R USI-822-RPC USI-824 USI-824-B USI-824-CE USI-824-R USI-824-RPC USI-826 USI-826-B USI-826-CE USI-826-R USI-826-RPC USI-828 USI-828-B USI-828-CE USI-828-R USI-828-RPC USI-830 USI-830-B USI-830-R USI-830-RPC			
BUDI-DI: 0827002CIRL202007020003AX Article Numbers: GEPD-10-12 GEPD-10-15 GEPD-10-3 GEPD-10-5 GEPD-10-7 GEPD-10-9 GEPD-11.5-6 GEPD-11.5-8 GEPD-11.5-10 GEPD-11.5-12 GEPD-3-10 GEPD-3-11 GEPD-3-12 GEPD-3-13 GEPD-3-14 GEPD-3-15 GEPD-3-3 GEPD-3-4 GEPD-3-5 GEPD-3-6 GEPD-3-7 GEPD-3-8 GEPD-3-9 GEPD-5-10 GEPD-5-11 GEPD-5-12 GEPD-5-13 GEPD-5-14 GEPD-5-15 GEPD-5-2	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb im- plantable (exempted) <input 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 cor- responding device under MDD/AIMDD Individual Article number: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) 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
GEPD-5-3 GEPD-5-4 GEPD-5-5 GEPD-5-6 GEPD-5-7 GEPD-5-8 GEPD-5-9 GEPD-7-10 GEPD-7-11 GEPD-7-12 GEPD-7-13 GEPD-7-14 GEPD-7-15 GEPD-7-3 GEPD-7-4 GEPD-7-5 GEPD-7-6 GEPD-7-7 GEPD-7-8 GEPD-7-9 GEPD-8.5-12 GEPD-8.5-3 GEPD-8.5-5 GEPD-8.5-7 GEPD-8.5-9 GPDS-5-15 GPDS-5-2 GPDS-5-12 GPDS-5-3 GPDS-5-5 GPDS-5-7 GPDS-5-9 GPDS-7-3 GPDS-7-12 GPDS-7-5 GPDS-7-7 GPDS-7-9 GPSO-7-20 GPSO-10-2 GPSO-10-10 GPSO-10-12 GPSO-10-15 GPSO-10-3 GPSO-10-5 GPSO-10-7 GPSO-10-9 GPSO-3-2 GPSO-3-10 GPSO-3-11 GPSO-3-12 GPSO-3-13 GPSO-3-14 GPSO-3-15 GPSO-3-3 GPSO-3-4 GPSO-3-5 GPSO-3-6 GPSO-3-7 GPSO-3-8 GPSO-3-9 GPSO-4-2 GPSO-4-5 GPSO-4-7 GPSO-4-9 GPSO-5-2 GPSO-5-9 GPSO-5-10 GPSO-5-11 GPSO-5-12 GPSO-5-13 GPSO-5-14 GPSO-5-15			



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
GPSO-5-18 GPSO-5-3 GPSO-5-4 GPSO-5-5 GPSO-5-6 GPSO-5-7 GPSO-5-8 GPSO-6-2 GPSO-6-3 GPSO-6-5 GPSO-6-7 GPSO-6-9 GPSO-6-12 GPSO-6-15 GPSO-7-2 GPSO-7-10 GPSO-7-11 GPSO-7-12 GPSO-7-13 GPSO-7-14 GPSO-7-15 GPSO-7-18 GPSO-7-3 GPSO-7-4 GPSO-7-5 GPSO-7-6 GPSO-7-7 GPSO-7-8 GPSO-7-9 GPSO-8.5-12 GPSO-8.5-15 GPSO-8.5-3 GPSO-8.5-5 GPSO-8.5-7 GPSO-8.5-9 GPSOS-5-2 GPSOS-5-3 GPSOS-5-4 GPSOS-5-5 GPSOS-5-7 GPSOS-5-9 GPSOS-5-12 GPSOS-5-15 GPSOS-7-2 GPSOS-7-3 GPSOS-7-5 GPSOS-7-7 GPSOS-7-9 GPSOS-7-10 GPSOS-7-12 GPSOS-7-15 SPSOF-10-10 SPSOF-10-12 SPSOF-10-15 SPSOF-10-3 SPSOF-10-4 SPSOF-10-5 SPSOF-10-6 SPSOF-10-7 SPSOF-10-8 SPSOF-4-2 SPSOF-4-4 SPSOF-4-6 SPSOF-4-8 SPSOF-4-10 SPSOF-4-12 SPSOF-4-15 SPSOF-4-18 SPSOF-5-9 SPSOF-5-10 SPSOF-5-11 SPSOF-5-12			



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
SPSOF-5-15 SPSOF-5-2 SPSOF-5-2.5 SPSOF-5-3 SPSOF-5-4 SPSOF-5-5 SPSOF-5-6 SPSOF-5-7 SPSOF-5-8 SPSOF-6-2 SPSOF-6-2.5 SPSOF-6-4 SPSOF-6-6 SPSOF-6-8 SPSOF-6-10 SPSOF-6-12 SPSOF-6-15 SPSOF-7-10 SPSOF-7-11 SPSOF-7-12 SPSOF-7-15 SPSOF-7-16 SPSOF-7-18 SPSOF-7-2 SPSOF-7-2.5 SPSOF-7-3 SPSOF-7-4 SPSOF-7-5 SPSOF-7-6 SPSOF-7-7 SPSOF-7-8 SPSOF-7-9 SPSOF-8.5-10 SPSOF-8.5-12 SPSOF-8.5-7 SPSOS-3-10-N SPSOS-3-12-N SPSOS-3-18-N SPSOS-3-4-N SPSOS-3-6-N SPSOS-3-8-N SPSOS-5-3 SPSOS-5-5 SPSOS-5-7 SPSOS-7-3 SPSOS-7-5 ZEPDF-5-9 ZEPDF-7-9 ZEPDF-5-10 ZEPDF-5-12 ZEPDF-5-2 ZEPDF-5-4 ZEPDF-5-5 ZEPDF-5-6 ZEPDF-5-7 ZEPDF-5-8 ZEPDF-7-10 ZEPDF-7-12 ZEPDF-7-15 ZEPDF-7-2 ZEPDF-7-4 ZEPDF-7-5 ZEPDF-7-6 ZEPDF-7-7 ZEPDF-7-8 ZEPDS-5-10 ZEPDS-5-12 ZEPDS-5-2 ZEPDS-5-4 ZEPDS-5-6 ZEPDS-5-8 ZEPDS-7-10			



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
ZEPDS-7-12 ZEPDS-7-4 ZEPDS-7-6 ZEPDS-7-8 ZPSOF-5-10 ZPSOF-5-12 ZPSOF-5-15 ZPSOF-5-2 ZPSOF-5-3 ZPSOF-5-4 ZPSOF-5-5 ZPSOF-5-6 ZPSOF-5-7 ZPSOF-5-8 ZPSOF-5-9 ZPSOF-7-10 ZPSOF-7-12 ZPSOF-7-15 ZPSOF-7-4 ZPSOF-7-6 ZPSOF-7-7 ZPSOF-7-8 ZPSOF-7-2 ZPSOF-7-9 ZPSOS-5-12 ZPSOS-5-3 ZPSOS-5-5 ZPSOS-5-7 ZPSOS-5-9 ZPSOS-7-10 ZPSOS-7-12 ZPSOS-7-4 ZPSOS-7-6 ZPSOS-7-25-NP ZPSOS-7-8 JPWS-8.5-10 JPWS-8.5-22 JPWS-8.5-12 JPWS-8.5-14 JPWS-8.5-16 JPWS-8.5-18 JPWS-8.5-20 JPWS-10-10 JPWS-10-12 JPWS-10-14 JPWS-10-16 JPWS-10-18 JPWS-10-20 JPWS-10-8 JPWS-8.5-8 JPWS-10-22 GPSO-SF-5-3 GPSO-SF-5-5 GPSO-SF-5-7 GPSO-SF-5-9 GPSO-SF-5-12 GPSOS-SF-5-3 GPSOS-SF-5-5 GPSOS-SF-5-7 GPSOS-SF-5-9 GPSOS-SF-5-12			



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
BUDI-DI: 0827002CIRL202009051015DG Article Numbers: ZVT7-35-80-14-6.0 ZVT7-35-80-14-10.0 ZVT7-35-80-14-14.0 ZVT7-35-80-16-6.0 ZVT7-35-80-16-10.0 ZVT7-35-80-16-14.0 ZVT7-35-120-14-6.0 ZVT7-35-120-14-10.0 ZVT7-35-120-14-14.0 ZVT7-35-120-16-6.0 ZVT7-35-120-16-10.0 ZVT7-35-120-16-14.0	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: 0827002CIRL202011049017BC Article Numbers: EVO-22-27-12-D EVO-22-27-6-D EVO-22-27-9-D	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: 0827002CIRL2020110500249M Article Numbers: ZIB6-40-8-4.0 ZIB6-40-8-6.0 ZIB6-40-8-8.0 ZIB6-40-9-4.0 ZIB6-40-9-6.0 ZIB6-40-9-8.0 ZIB6-40-10-4.0 ZIB6-40-10-6.0 ZIB6-40-10-8.0 ZIB6-40-12-4.0 ZIB6-40-12-6.0 ZIB6-40-12-8.0 ZIB6-40-14-4.0 ZIB6-40-14-6.0 ZIB6-40-14-8.0 ZIB6-40-6-4.0 ZIB6-40-6-6.0 ZIB6-40-6-8.0	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: 0827002CIRL202011055020AG Article Numbers: ZFV6-125-5-2.0 ZFV6-125-5-3.0	<input type="checkbox"/> Class III <input checked="" 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: Certificate # G1 033038 0037 Rev.00; NB# 0123 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
ZFV6-125-5-4.0 ZFV6-125-5-6.0 ZFV6-125-5-8.0 ZFV6-125-5-10.0 ZFV6-125-5-12.0 ZFV6-125-5-14.0 ZFV6-125-5-17.0 ZFV6-125-6-2.0 ZFV6-125-6-3.0 ZFV6-125-6-4.0 ZFV6-125-6-6.0 ZFV6-125-6-8.0 ZFV6-125-6-10.0 ZFV6-125-6-12.0 ZFV6-125-6-14.0 ZFV6-125-7-2.0 ZFV6-125-7-3.0 ZFV6-125-7-4.0 ZFV6-125-7-6.0 ZFV6-125-7-8.0 ZFV6-125-7-10.0 ZFV6-125-7-12.0 ZFV6-125-7-14.0 ZFV6-125-8-2.0 ZFV6-125-8-3.0 ZFV6-125-8-4.0 ZFV6-125-8-6.0 ZFV6-125-8-8.0 ZFV6-125-8-10.0 ZFV6-125-8-12.0 ZFV6-125-8-14.0 ZFV6-125-9-2.0 ZFV6-125-9-3.0 ZFV6-125-9-4.0 ZFV6-125-9-6.0 ZFV6-125-9-8.0 ZFV6-125-9-10.0 ZFV6-125-9-12.0 ZFV6-125-9-14.0 ZFV6-125-10-2.0 ZFV6-125-10-3.0 ZFV6-125-10-4.0 ZFV6-125-10-6.0 ZFV6-125-10-8.0 ZFV6-125-10-10.0 ZFV6-125-10-12.0 ZFV6-125-10-14.0 ZFV6-125-5-20.0 ZFV6-125-6-17.0 ZFV6-125-6-20.0 ZFV6-125-7-17.0 ZFV6-125-7-20.0 ZFV6-125-8-17.0 ZFV6-125-8-20.0 ZFV6-80-5-2.0 ZFV6-80-5-3.0 ZFV6-80-5-4.0 ZFV6-80-5-6.0 ZFV6-80-5-8.0 ZFV6-80-5-10.0 ZFV6-80-5-12.0 ZFV6-80-5-14.0 ZFV6-80-6-2.0 ZFV6-80-6-3.0 ZFV6-80-6-4.0 ZFV6-80-6-6.0 ZFV6-80-6-8.0 ZFV6-80-6-10.0 ZFV6-80-6-12.0 ZFV6-80-6-14.0 ZFV6-80-7-2.0 ZFV6-80-7-3.0	<input 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"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: N/A	<input type="checkbox"/> Evidence that a competent authority of a Member State has 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
ZFV6-80-7-4.0 ZFV6-80-7-6.0 ZFV6-80-7-8.0 ZFV6-80-7-10.0 ZFV6-80-7-12.0 ZFV6-80-7-14.0 ZFV6-80-8-2.0 ZFV6-80-8-3.0 ZFV6-80-8-4.0 ZFV6-80-8-6.0 ZFV6-80-8-8.0 ZFV6-80-8-10.0 ZFV6-80-8-12.0 ZFV6-80-8-14.0 ZFV6-80-9-2.0 ZFV6-80-9-3.0 ZFV6-80-9-4.0 ZFV6-80-9-6.0 ZFV6-80-9-8.0 ZFV6-80-9-10.0 ZFV6-80-9-12.0 ZFV6-80-9-14.0 ZFV6-80-10-10.0 ZFV6-80-10-12.0 ZFV6-80-10-14.0 ZFV6-80-10-2.0 ZFV6-80-10-3.0 ZFV6-80-10-4.0 ZFV6-80-10-6.0 ZFV6-80-10-8.0 ZFV6-80-5-17.0 ZFV6-80-5-20.0 ZFV6-80-6-17.0 ZFV6-80-6-20.0 ZFV6-80-7-17.0 ZFV6-80-8-17.0 ZFV6-80-8-20.0 ZFV6-80-7-20.0			
BUDI-DI: 0827002CIRL202011056021AR Article Numbers: ZIV5-80-4-2.0 ZIV5-80-4-3.0 ZIV5-80-4-4.0 ZIV5-80-4-6.0 ZIV5-80-4-8.0 ZIV5-80-5-2.0 ZIV5-80-5-3.0 ZIV5-80-5-4.0 ZIV5-80-5-6.0 ZIV5-80-5-8.0 ZIV5-80-6-2.0 ZIV5-80-6-3.0 ZIV5-80-6-4.0 ZIV5-80-6-6.0 ZIV5-80-6-8.0 ZIV5-80-7-2.0 ZIV5-80-7-3.0 ZIV5-80-7-4.0 ZIV5-80-7-6.0 ZIV5-80-7-8.0 ZIV5-80-8-2.0 ZIV5-80-8-3.0 ZIV5-80-8-4.0 ZIV5-80-8-6.0 ZIV5-80-8-8.0 ZIV5-80-9-2.0 ZIV5-80-9-3.0 ZIV5-80-9-4.0	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) 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
ZIV5-80-9-6.0 ZIV5-80-9-8.0 ZIV5-80-10-2.0 ZIV5-80-10-3.0 ZIV5-80-10-4.0 ZIV5-80-10-6.0 ZIV5-80-10-8.0 ZIV5-125-4-2.0 ZIV5-125-4-3.0 ZIV5-125-4-4.0 ZIV5-125-4-6.0 ZIV5-125-4-8.0 ZIV5-125-5-2.0 ZIV5-125-5-3.0 ZIV5-125-5-4.0 ZIV5-125-5-6.0 ZIV5-125-5-8.0 ZIV5-125-6-2.0 ZIV5-125-6-3.0 ZIV5-125-6-4.0 ZIV5-125-6-6.0 ZIV5-125-6-8.0 ZIV5-125-7-2.0 ZIV5-125-7-3.0 ZIV5-125-7-4.0 ZIV5-125-7-6.0 ZIV5-125-7-8.0 ZIV5-125-8-2.0 ZIV5-125-8-3.0 ZIV5-125-8-4.0 ZIV5-125-8-6.0 ZIV5-125-8-8.0 ZIV5-125-9-2.0 ZIV5-125-9-3.0 ZIV5-125-9-4.0 ZIV5-125-9-6.0 ZIV5-125-9-8.0 ZIV5-125-10-2.0 ZIV5-125-10-3.0 ZIV5-125-10-4.0 ZIV5-125-10-6.0 ZIV5-125-10-8.0 ZIV6-80-5-2.0 ZIV6-80-5-3.0 ZIV6-80-5-4.0 ZIV6-80-5-6.0 ZIV6-80-5-8.0 ZIV6-80-6-2.0 ZIV6-80-6-3.0 ZIV6-80-6-4.0 ZIV6-80-6-6.0 ZIV6-80-6-8.0 ZIV6-80-7-2.0 ZIV6-80-7-3.0 ZIV6-80-7-4.0 ZIV6-80-7-6.0 ZIV6-80-7-8.0 ZIV6-80-8-2.0 ZIV6-80-8-3.0 ZIV6-80-8-4.0 ZIV6-80-8-6.0 ZIV6-80-8-8.0 ZIV6-80-9-2.0 ZIV6-80-9-3.0 ZIV6-80-9-4.0 ZIV6-80-9-6.0 ZIV6-80-9-8.0 ZIV6-80-10-2.0 ZIV6-80-10-3.0 ZIV6-80-10-4.0 ZIV6-80-10-6.0 ZIV6-80-10-8.0			



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
ZIV6-80-12-3.0 ZIV6-80-12-4.0 ZIV6-80-12-6.0 ZIV6-80-12-8.0 ZIV6-80-14-3.0 ZIV6-80-14-4.0 ZIV6-80-14-6.0 ZIV6-80-14-8.0 ZIV6-125-5-2.0 ZIV6-125-5-3.0 ZIV6-125-5-4.0 ZIV6-125-5-6.0 ZIV6-125-5-8.0 ZIV6-125-6-2.0 ZIV6-125-6-3.0 ZIV6-125-6-4.0 ZIV6-125-6-6.0 ZIV6-125-6-8.0 ZIV6-125-7-2.0 ZIV6-125-7-3.0 ZIV6-125-7-4.0 ZIV6-125-7-6.0 ZIV6-125-7-8.0 ZIV6-125-8-2.0 ZIV6-125-8-3.0 ZIV6-125-8-4.0 ZIV6-125-8-6.0 ZIV6-125-8-8.0 ZIV6-125-9-2.0 ZIV6-125-9-3.0 ZIV6-125-9-4.0 ZIV6-125-9-6.0 ZIV6-125-9-8.0 ZIV6-125-10-2.0 ZIV6-125-10-3.0 ZIV6-125-10-4.0 ZIV6-125-10-6.0 ZIV6-125-10-8.0 ZIV6-125-12-3.0 ZIV6-125-12-4.0 ZIV6-125-12-6.0 ZIV6-125-12-8.0 ZIV6-125-14-3.0 ZIV6-125-14-4.0 ZIV6-125-14-6.0 ZIV6-125-14-8.0			
BUDI-DI: 0827002CIRL202011064022AQ Article Numbers: EVO-PC-8-9-6-B EVO-PC-8-9-8-B EVO-PC-10-11-4-B EVO-PC-10-11-6-B EVO-PC-10-11-8-B EVO-FC-8-9-6-B EVO-FC-8-9-8-B EVO-FC-10-11-4-B EVO-FC-10-11-6-B EVO-FC-10-11-8-B	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: 0827002CIRL202309008036FP Article Numbers: UFI-522	<input type="checkbox"/> Class III <input checked="" 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: Certificate # G1 033038 0037 Rev.00; NB# 0123 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
UFI-524 UFI-526 UFI-528 UFI-530 UFI-622 UFI-624 UFI-626 UFI-628 UFI-630 UFI-722 UFI-724 UFI-726 UFI-728 UFI-822 UFI-824 UFI-826 UFI-828 UFI-500 UFI-600 UFI-700 UFI-522-R UFI-524-R UFI-526-R UFI-528-R UFI-622-R UFI-624-R UFI-626-R UFI-628-R UFI-722-R UFI-724-R UFI-726-R UFI-728-R UFI-822-R UFI-824-R UFI-826-R UFI-828-R UFI-500-R UFI-600-R UFI-700-R UFI-622-B UFI-624-B UFI-626-B UFI-726-B UFI-500-B UFI-600-B UFI-700-B UFI-522-RPC-LP UFI-524-RPC-LP UFI-526-RPC-LP UFI-528-RPC-LP UFI-622-RPC-LP UFI-624-RPC-LP UFI-626-RPC-LP UFI-628-RPC-LP UFI-722-RPC-LP UFI-724-RPC-LP UFI-726-RPC-LP UFI-728-RPC-LP UFI-500-RPC-LP UFI-600-RPC-LP UFI-700-RPC-LP UFI-626-LP UFI-724-LP UFI-726-P UFI-728-P UFI-626-P UFI-628-P UFI-500-LP UFI-600-LP UFI-700-LP	<input 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"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: N/A	<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
BUDI-DI: 0827002CIRL202011065016B4 Article Numbers: EVO-8-9-4-B EVO-8-9-6-B EVO-8-9-8-B EVO-8-9-10-B EVO-10-11-4-B EVO-10-11-6-B EVO-10-11-8-B EVO-10-11-10-B	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: 0827002CIRL202011063030AG Article Numbers: ZILBS-635-10-4 ZILBS-635-10-6 ZILBS-635-10-8 ZILBS-635-6-4 ZILBS-635-6-6 ZILBS-635-6-8 ZILBS-635-8-4 ZILBS-635-8-6 ZILBS-635-8-8 ZILBS-635-10-10 ZILBS-635-10-12 ZILBS-635-8-10 ZILBS-635-8-12 ZILBS-635-6-10 ZILBS-635-6-12	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: 0827002CIRL202011068027BW Article Numbers: EVO-25-30-10-C EVO-25-30-6-C EVO-25-30-8-C	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: 0827002CIRL202011069028C7 Article Numbers: EVO-20-25-10-E EVO-20-25-12.5-E EVO-20-25-15-E EVO-20-25-8-E EVO-FC-18-23-10-E EVO-FC-18-23-12-E EVO-FC-18-23-8-E	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State



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
EVO-FC-20-25-10-E EVO-FC-20-25-12-E EVO-FC-20-25-8-E	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: 0827002CIRL202011070029AM Article Numbers: EVO-FC-R-18-23-10-E EVO-FC-R-18-23-12-E EVO-FC-R-18-23-8-E EVO-FC-R-20-25-10-E EVO-FC-R-20-25-12-E EVO-FC-R-20-25-8-E	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BUDI-DI: 0827002CIRL202007013010B6 Article Numbers: OACL-10-5 OACL-10-7 OACL-10-9 OACL-10-12 OACL-10-15 OACL-8.5-5 OACL-8.5-7 OACL-8.5-9 OACL-8.5-12 OACL-8.5-15 OACL-7-5 OACL-7-7 OACL-7-9 OACL-7-12 OACL-7-15 OACL-11.5-5 OACL-11.5-7 OACL-11.5-9 OACL-11.5-12 OACL-11.5-15 OATS-8.5-5 OATS-8.5-7 OATS-8.5-9 OATS-8.5-12 OATS-8.5-15 OATS-10-5 OATS-10-7 OATS-10-9 OATS-10-12 OATS-10-15 OATS-11.5-5 OATS-11.5-7 OATS-11.5-9 OATS-11.5-12 OATS-11.5-15 ZSS-10-1-RB ZSS-10-3-RB ZSS-10-4-RB ZSS-10-5-RB ZSS-10-7-RB ZSS-10-9-RB ZSS-10-10-RB	<input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input 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: N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 033038 0037 Rev.00; NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) 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
ZSS-10-12-RB ZSS-10-15-RB CHBS-10-3 CHBS-10-5 CHBS-10-7 CHBS-10-9 CHBS-10-10 CHBS-10-11 CHBS-10-12 CHBS-10-15 CHBS-11.5-5 CHBS-11.5-7 CHBS-11.5-9 CHBS-11.5-10 CHBS-11.5-12 CHBS-11.5-15 CHBS-7-3 CHBS-7-5 CHBS-7-6 CHBS-7-7 CHBS-7-9 CHBS-7-10 CHBS-7-12 CHBS-7-15 CHBS-8.5-5 CHBS-8.5-7 CHBS-8.5-9 CHBS-8.5-12 CHBS-8.5-15 CHBSO-10-3 CHBSO-10-4 CHBSO-10-5 CHBSO-10-6 CHBSO-10-7 CHBSO-10-8 CHBSO-10-9 CHBSO-10-10 CHBSO-10-11 CHBSO-10-12 CHBSO-10-15 CHBSO-10-18 CHBSO-11.5-5 CHBSO-11.5-7 CHBSO-11.5-8 CHBSO-11.5-9 CHBSO-11.5-10 CHBSO-11.5-12 CHBSO-11.5-15 CHBSO-11.5-18 CHBSO-7-4 CHBSO-7-5 CHBSO-7-7 CHBSO-7-9 CHBSO-7-10 CHBSO-7-12 CHBSO-7-15 CHBSO-7-18 CHBSO-8.5-5 CHBSO-8.5-7 CHBSO-8.5-9 CHBSO-8.5-10 CHBSO-8.5-12 CHBSO-8.5-15 CHBSO-8.5-18 CLBS-10-3 CLBS-10-4 CLBS-10-5 CLBS-10-6 CLBS-10-7 CLBS-10-8 CLBS-10-9 CLBS-10-10			



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
CLBS-10-11 CLBS-10-12 CLBS-10-13 CLBS-10-14 CLBS-10-15 CLBS-10-16 CLBS-10-17 CLBS-10-18 CLBS-11.5-3 CLBS-11.5-5 CLBS-11.5-6 CLBS-11.5-7 CLBS-11.5-8 CLBS-11.5-9 CLBS-11.5-10 CLBS-11.5-11 CLBS-11.5-12 CLBS-11.5-13 CLBS-11.5-14 CLBS-11.5-15 CLBS-11.5-16 CLBS-11.5-17 CLBS-11.5-18 CLBS-5-5 CLBS-5-7 CLBS-5-9 CLBS-5-12 CLBS-7-3 CLBS-7-4 CLBS-7-5 CLBS-7-6 CLBS-7-7 CLBS-7-8 CLBS-7-9 CLBS-7-10 CLBS-7-11 CLBS-7-12 CLBS-7-13 CLBS-7-14 CLBS-7-15 CLBS-7-16 CLBS-7-17 CLBS-7-18 CLBS-8.5-3 CLBS-8.5-5 CLBS-8.5-6 CLBS-8.5-7 CLBS-8.5-8 CLBS-8.5-9 CLBS-8.5-10 CLBS-8.5-11 CLBS-8.5-12 CLBS-8.5-13 CLBS-8.5-14 CLBS-8.5-15 CLBS-8.5-16 CLBS-8.5-17 CLBS-8.5-18 CLSO-5-3 CLSO-5-5 CLSO-5-7 CLSO-5-9 CLSO-5-12 CLSO-5-15 CLSO-7-2 CLSO-7-3 CLSO-7-4 CLSO-7-5 CLSO-7-6 CLSO-7-7 CLSO-7-8 CLSO-7-9			



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
CLSO-7-10 CLSO-7-11 CLSO-7-12 CLSO-7-13 CLSO-7-14 CLSO-7-15 CLSO-7-16 CLSO-7-17 CLSO-7-18 CLSO-7-19 CLSO-7-20 CLSO-7-21 CLSO-8.5-3 CLSO-8.5-5 CLSO-8.5-6 CLSO-8.5-7 CLSO-8.5-8 CLSO-8.5-9 CLSO-8.5-10 CLSO-8.5-11 CLSO-8.5-12 CLSO-8.5-13 CLSO-8.5-14 CLSO-8.5-15 CLSO-8.5-16 CLSO-8.5-17 CLSO-8.5-18 CLSO-8.5-20 CLSO-10-2 CLSO-10-3 CLSO-10-4 CLSO-10-5 CLSO-10-6 CLSO-10-7 CLSO-10-8 CLSO-10-9 CLSO-10-10 CLSO-10-11 CLSO-10-12 CLSO-10-13 CLSO-10-14 CLSO-10-15 CLSO-10-16 CLSO-10-17 CLSO-10-18 CLSO-10-19 CLSO-10-20 CLSO-10-21 CLSO-11.5-3 CLSO-11.5-5 CLSO-11.5-6 CLSO-11.5-7 CLSO-11.5-8 CLSO-11.5-9 CLSO-11.5-10 CLSO-11.5-11 CLSO-11.5-12 CLSO-11.5-13 CLSO-11.5-14 CLSO-11.5-15 CLSO-11.5-16 CLSO-11.5-17 CLSO-11.5-18 CLSO-11.5-20 PBS-7-5 PBS-7-7 PBS-7-9 PBS-7-12 PBS-7-15 PBS-8.5-5 PBS-8.5-7 PBS-8.5-9			



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
PBS-8.5-12 PBS-8.5-15 PBS-10-5 PBS-10-7 PBS-10-9 PBS-10-12 PBS-10-15 PBS-11.5-5 PBS-11.5-7 PBS-11.5-9 PBS-11.5-12 PBS-11.5-15 TTSO-10-5 TTSO-10-6 TTSO-10-7 TTSO-10-8 TTSO-10-9 TTSO-10-10 TTSO-10-11 TTSO-10-12 TTSO-10-13 TTSO-10-14 TTSO-10-15 TTSO-11.5-5 TTSO-11.5-6 TTSO-11.5-7 TTSO-11.5-8 TTSO-11.5-9 TTSO-11.5-10 TTSO-11.5-11 TTSO-11.5-12 TTSO-11.5-13 TTSO-11.5-14 TTSO-11.5-15 TTSO-8.5-5 TTSO-8.5-6 TTSO-8.5-7 TTSO-8.5-8 TTSO-8.5-9 TTSO-8.5-10 TTSO-8.5-11 TTSO-8.5-12 TTSO-8.5-13 TTSO-8.5-14 TTSO-8.5-15 ZEBD-10-2 ZEBD-10-3 ZEBD-10-4 ZEBD-10-5 ZEBD-10-6 ZEBD-10-7 ZEBD-10-8 ZEBD-10-9 ZEBD-10-10 ZEBD-10-12 ZEBD-10-15 ZEBD-5-3 ZEBD-5-4 ZEBD-5-5 ZEBD-5-7 ZEBD-5-9 ZEBD-5-10 ZEBD-5-12 ZEBD-5-15 ZEBD-6-4 ZEBD-6-7 ZEBD-6-10 ZEBD-6-12 ZEBD-7-2 ZEBD-7-3 ZEBD-7-4 ZEBD-7-5			



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
ZEBD-7-7 ZEBD-7-6 ZEBD-7-8 ZEBD-7-9 ZEBD-7-10 ZEBD-7-12 ZEBD-7-15 ZEBD-7-18 ZEBD-8-5 ZEBD-8-7 ZEBD-8-9 ZEBD-8-12 ZEBD-8-15 ZSO-10-2 ZSO-10-3 ZSO-10-4 ZSO-10-5 ZSO-10-6 ZSO-10-7 ZSO-10-8 ZSO-10-9 ZSO-10-10 ZSO-10-12 ZSO-10-15 ZSO-5-3 ZSO-5-4 ZSO-5-5 ZSO-5-7 ZSO-5-9 ZSO-5-10 ZSO-5-12 ZSO-5-15 ZSO-6-4 ZSO-6-7 ZSO-6-9 ZSO-6-10 ZSO-7-3 ZSO-7-4 ZSO-7-5 ZSO-7-6 ZSO-7-7 ZSO-7-9 ZSO-7-10 ZSO-7-12 ZSO-7-15 ZSO-7-16 ZSO-7-18 ZSO-8-4 ZSO-8-5 ZSO-8-7 ZSO-8-9 ZSO-8-10 ZSO-8-12 ZSO-8-15 CLSO-SF-7-5 CLSO-SF-7-7 CLSO-SF-7-9 CLSO-SF-7-12 CLSO-SF-7-15 CLSO-SF-10-5 CLSO-SF-10-7 CLSO-SF-10-9 CLSO-SF-10-12 CLSO-SF-10-15			



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

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-01-26	713212698	Initial issue