Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Masurenweg 1-3 · 30163 Hannover · Germany

ulrich GmbH & Co. KG
Buchbrunnenweg 12
89081 Ulm
Germany

Your reference/letter of	Our reference/name	Email	Fax extension	Date	Page
11099	713316966 | 713315823	medical_devices@tuvsud.com	-	2024-04-11	1 of 31

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 011099 0514 Rev. 00

Reference: 713316966 | 713315823

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-000006411

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 011099 0514 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

Sabine Koeberlein
Sabine Koeberlein (Apr 11, 2024 14:14 GMT+2)

Sabine Köberlein
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Apr 11, 2024 13:21 GMT+2)

Michael Mauermeir
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
4052536000007PS: CS 3843-01 CS 3843-02 CS 3843-03 CS 3843-04 CS 3843-05 CS 3843-06 CS 3843-07 CS 3843-08	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000008PU: CS 3850-01 CS 3850-02 E02971-01 E02971-02	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000039Q7: XD 10701 XD 10702 XD 10703 XD 10707 XD 2035 XD 2037 XD 2040 XD 2042 XD 2045 XD 2047	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000040PQ: XD 10704 XD 10705 XD 10706 XD 10710 XD 10711 XD 10712 XD 10713 XD 10716 XD 10717	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000041PS: XD 2020 XD 8002 XD 8003 XD 8132 XD 8151	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000061PY: CS 1482-30 CS 3922-410 CS 3922-530 CS 3926-03 CS 3927-03 CS 3951-03 CS 3951-04	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000079QK: CS 7175-075	☒ Class IIa	☒ N/A	☒ 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
CS 7175-075-01 CS 7175-085 CS 7175-085-01 CS 7175-100 CS 7175-100-01			G1 011099 0060 Rev. 01, NB 0123
4052536000080Q4 CS 3962-01	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000044PY: XD 8000	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000043PW: XD 10130 XD 10160	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000159QJ: CS 2605	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123 G7 011099 0507 Rev. 00, NB 0123
4052536000160Q3: CS 2608-040 CS 2608-050 CS 2608-060 CS 2608-070 CS 2608-080 CS 2608-090 CS 2608-100 CS 2608-110 CS 2608-120 CS 2608-200	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123 G7 011099 0507 Rev. 00, NB 0123
4052536000000PC: CS 3801-01-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000001PE: CS 3801-02-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000077QF: CS 7170-075-040-S CS 7170-075-050-S CS 7170-075-060-S CS 7170-075-070-S CS 7170-075-080-S CS 7170-085-060-S CS 7170-085-070-S CS 7170-085-080-S CS 7170-085-090-S CS 7170-085-100-S CS 7170-085-110-S CS 7170-085-120-S CS 7170-100-080-S CS 7170-100-090-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 7170-100-100-S CS 7170-100-110-S CS 7170-100-120-S CS 7170-100-130-S CS 7170-100-140-S			
4052536000078QH: CS 7171-06-01-S CS 7171-06-02-S CS 7171-06-03-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000082Q8: CS 3807-030-S CS 3807-035-S CS 3807-040-S CS 3807-045-S CS 3807-050-S CS 3807-055-S CS 3807-060-S CS 3807-065-S CS 3807-070-S CS 3807-075-S CS 3807-080-S CS 3807-085-S CS 3807-090-S CS 3807-095-S CS 3807-100-S CS 3807-110-S CS 3807-120-S CS 3807-132-S CS 3807-144-S CS 3807-156-S CS 3807-168-S CS 3807-180-S CS 3807-200-S CS 3807-300-S CS 3807-400-S CS 3807-500-S CS 3808-030-S CS 3808-035-S CS 3808-040-S CS 3808-045-S CS 3808-050-S CS 3808-055-S CS 3808-060-S CS 3808-065-S CS 3808-070-S CS 3808-075-S CS 3808-080-S CS 3808-085-S CS 3808-090-S CS 3808-095-S CS 3808-100-S CS 3808-110-S CS 3808-120-S CS 3808-132-S CS 3808-144-S CS 3808-156-S CS 3808-168-S CS 3808-180-S CS 3808-200-S CS 3808-300-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3808-400-S CS 3808-500-S CS 3809-030-S CS 3809-035-S CS 3809-040-S CS 3809-045-S CS 3809-050-S CS 3809-055-S CS 3809-060-S CS 3809-065-S CS 3809-070-S CS 3809-075-S CS 3809-080-S CS 3812-400-S			
4052536000083QA: CS 3802-045-025 CS 3802-045-030 CS 3802-045-035 CS 3802-045-040 CS 3802-045-045 CS 3802-045-050 CS 3802-055-025 CS 3802-055-030 CS 3802-055-035 CS 3802-055-040 CS 3802-055-045 CS 3802-055-050 CS 3802-055-055 CS 3802-065-030 CS 3802-065-035 CS 3802-065-040 CS 3802-065-045 CS 3802-065-050 CS 3802-065-055 CS 3802-065-060 CS 3802-075-035 CS 3802-075-040 CS 3802-075-045 CS 3802-075-050 CS 3802-075-055 CS 3802-075-060 CS 3802-085-035 CS 3802-085-040 CS 3802-085-045 CS 3802-085-050 CS 3802-085-055 CS 3802-085-060 CS 3802-100-045 CS 3802-100-050 CS 3802-100-055 CS 3802-100-060 CS 3872-055-025 CS 3872-055-030 CS 3872-055-035 CS 3872-055-040 CS 3872-055-045 CS 3872-055-050 CS 3872-055-055 CS 3872-065-030 CS 3872-065-035	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3872-065-040 CS 3872-065-045 CS 3872-065-050 CS 3872-065-055 CS 3872-065-060 CS 3872-075-035 CS 3872-075-040 CS 3872-075-045 CS 3872-075-050 CS 3872-075-055 CS 3872-075-060 CS 3872-085-035 CS 3872-085-040 CS 3872-085-045 CS 3872-085-050 CS 3872-085-055 CS 3872-085-060 CS 3872-100-045 CS 3872-100-050 CS 3872-100-055 CS 3872-100-060			
4052536000084QC: CS 3803-045-025 CS 3803-045-030 CS 3803-045-035 CS 3803-045-040 CS 3803-045-045 CS 3803-045-050 CS 3803-055-025 CS 3803-055-030 CS 3803-055-035 CS 3803-055-040 CS 3803-055-045 CS 3803-055-050 CS 3803-055-055 CS 3803-065-030 CS 3803-065-035 CS 3803-065-040 CS 3803-065-045 CS 3803-065-050 CS 3803-065-055 CS 3803-065-060 CS 3803-075-035 CS 3803-075-040 CS 3803-075-045 CS 3803-075-050 CS 3803-075-055 CS 3803-075-060 CS 3803-085-035 CS 3803-085-040 CS 3803-085-045 CS 3803-085-050 CS 3803-085-055 CS 3803-085-060 CS 3803-100-045 CS 3803-100-050 CS 3803-100-055 CS 3803-100-060 CS 3873-055-025 CS 3873-055-030	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3873-055-035 CS 3873-055-040 CS 3873-055-045 CS 3873-055-050 CS 3873-055-055 CS 3873-065-030 CS 3873-065-035 CS 3873-065-040 CS 3873-065-045 CS 3873-065-050 CS 3873-065-055 CS 3873-065-060 CS 3873-075-035 CS 3873-075-040 CS 3873-075-045 CS 3873-075-050 CS 3873-075-055 CS 3873-075-060 CS 3873-085-035 CS 3873-085-040 CS 3873-085-045 CS 3873-085-050 CS 3873-085-055 CS 3873-085-060 CS 3873-100-045 CS 3873-100-050 CS 3873-100-055 CS 3873-100-060			
4052536000085QE: CS 3804-045-025 CS 3804-045-030 CS 3804-045-035 CS 3804-045-040 CS 3804-045-045 CS 3804-045-050 CS 3804-055-025 CS 3804-055-030 CS 3804-055-035 CS 3804-055-040 CS 3804-055-045 CS 3804-055-050 CS 3804-055-055 CS 3804-065-030 CS 3804-065-035 CS 3804-065-040 CS 3804-065-045 CS 3804-065-050 CS 3804-065-055 CS 3804-065-060 CS 3804-075-035 CS 3804-075-040 CS 3804-075-045 CS 3804-075-050 CS 3804-075-055 CS 3804-075-060 CS 3804-085-035 CS 3804-085-040 CS 3804-085-045 CS 3804-085-050 CS 3804-085-055	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3804-085-060 CS 3804-100-045 CS 3804-100-050 CS 3804-100-055 CS 3804-100-060 CS 3874-055-025 CS 3874-055-030 CS 3874-055-035 CS 3874-055-040 CS 3874-055-045 CS 3874-055-050 CS 3874-055-055 CS 3874-065-030 CS 3874-065-035 CS 3874-065-040 CS 3874-065-045 CS 3874-065-050 CS 3874-065-055 CS 3874-065-060 CS 3874-075-035 CS 3874-075-040 CS 3874-075-045 CS 3874-075-050 CS 3874-075-055 CS 3874-075-060 CS 3874-085-035 CS 3874-085-040 CS 3874-085-045 CS 3874-085-050 CS 3874-085-055 CS 3874-085-060 CS 3874-100-045 CS 3874-100-050 CS 3874-100-055 CS 3874-100-060			
4052536000086QG: CS 3805-055-025 CS 3805-055-030 CS 3805-055-035 CS 3805-055-040 CS 3805-055-045 CS 3805-055-050 CS 3805-055-055 CS 3805-065-030 CS 3805-065-035 CS 3805-065-040 CS 3805-065-045 CS 3805-065-050 CS 3805-065-055 CS 3805-065-060 CS 3805-075-035 CS 3805-075-040 CS 3805-075-045 CS 3805-075-050 CS 3805-075-055 CS 3805-075-060 CS 3805-085-035 CS 3805-085-040 CS 3805-085-045 CS 3805-085-050	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3805-085-055 CS 3805-085-060 CS 3875-055-025 CS 3875-055-030 CS 3875-055-035 CS 3875-055-040 CS 3875-055-045 CS 3875-055-050 CS 3875-055-055 CS 3875-065-030 CS 3875-065-035 CS 3875-065-040 CS 3875-065-045 CS 3875-065-050 CS 3875-065-055 CS 3875-065-060 CS 3875-075-035 CS 3875-075-040 CS 3875-075-045 CS 3875-075-050 CS 3875-075-055 CS 3875-075-060 CS 3875-085-035 CS 3875-085-040 CS 3875-085-045 CS 3875-085-050 CS 3875-085-055 CS 3875-085-060			
4052536000087QJ: CS 3882-045-025 CS 3882-045-030 CS 3882-045-035 CS 3882-045-040 CS 3882-045-045 CS 3882-045-050 CS 3882-055-025 CS 3882-055-030 CS 3882-055-035 CS 3882-055-040 CS 3882-055-045 CS 3882-055-050 CS 3882-055-055 CS 3882-065-030 CS 3882-065-035 CS 3882-065-040 CS 3882-065-045 CS 3882-065-050 CS 3882-065-055 CS 3882-065-060 CS 3882-075-035 CS 3882-075-040 CS 3882-075-045 CS 3882-075-050 CS 3882-075-055 CS 3882-075-060 CS 3882-085-035 CS 3882-085-040 CS 3882-085-045 CS 3882-085-050 CS 3882-085-055	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3882-085-060 CS 3882-100-045 CS 3882-100-050 CS 3882-100-055 CS 3882-100-060			
4052536000088QL: CS 3883-045-025 CS 3883-045-030 CS 3883-045-035 CS 3883-045-040 CS 3883-045-045 CS 3883-045-050 CS 3883-055-025 CS 3883-055-030 CS 3883-055-035 CS 3883-055-040 CS 3883-055-045 CS 3883-055-050 CS 3883-055-055 CS 3883-065-030 CS 3883-065-035 CS 3883-065-040 CS 3883-065-045 CS 3883-065-050 CS 3883-065-055 CS 3883-065-060 CS 3883-075-035 CS 3883-075-040 CS 3883-075-045 CS 3883-075-050 CS 3883-075-055 CS 3883-075-060 CS 3883-085-035 CS 3883-085-040 CS 3883-085-045 CS 3883-085-050 CS 3883-085-055 CS 3883-085-060 CS 3883-100-045 CS 3883-100-050 CS 3883-100-055 CS 3883-100-060	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000089QN: CS 3884-045-025 CS 3884-045-030 CS 3884-045-035 CS 3884-045-040 CS 3884-045-045 CS 3884-045-050 CS 3884-055-025 CS 3884-055-030 CS 3884-055-035 CS 3884-055-040 CS 3884-055-045 CS 3884-055-050 CS 3884-055-055 CS 3884-065-030 CS 3884-065-035 CS 3884-065-040 CS 3884-065-045	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3884-065-050 CS 3884-065-055 CS 3884-065-060 CS 3884-075-035 CS 3884-075-040 CS 3884-075-045 CS 3884-075-050 CS 3884-075-055 CS 3884-075-060 CS 3884-085-035 CS 3884-085-040 CS 3884-085-045 CS 3884-085-050 CS 3884-085-055 CS 3884-085-060 CS 3884-100-045 CS 3884-100-050 CS 3884-100-055 CS 3884-100-060			
4052536000090Q7: CS 3885-055-025 CS 3885-055-030 CS 3885-055-035 CS 3885-055-040 CS 3885-055-045 CS 3885-055-050 CS 3885-055-055 CS 3885-065-030 CS 3885-065-035 CS 3885-065-040 CS 3885-065-045 CS 3885-065-050 CS 3885-065-055 CS 3885-065-060 CS 3885-075-035 CS 3885-075-040 CS 3885-075-045 CS 3885-075-050 CS 3885-075-055 CS 3885-075-060 CS 3885-085-035 CS 3885-085-040 CS 3885-085-045 CS 3885-085-050 CS 3885-085-055 CS 3885-085-060	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000091Q9: CS 3810-00-S CS 3810-01-S CS 3810-02-S CS 3810-03-S CS 3810-04-S CS 3810-05-S CS 3810-10-S CS 3810-11-S CS 3810-12-S CS 3810-13-S CS 3810-14-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
4052536000093QD: CS 3882-045-025-S CS 3882-045-030-S CS 3882-045-035-S CS 3882-045-040-S CS 3882-045-045-S CS 3882-045-050-S CS 3882-055-025-S CS 3882-055-030-S CS 3882-055-035-S CS 3882-055-040-S CS 3882-055-045-S CS 3882-055-050-S CS 3882-055-055-S CS 3882-065-030-S CS 3882-065-035-S CS 3882-065-040-S CS 3882-065-045-S CS 3882-065-050-S CS 3882-065-055-S CS 3882-065-060-S CS 3882-075-035-S CS 3882-075-040-S CS 3882-075-045-S CS 3882-075-050-S CS 3882-075-055-S CS 3882-075-060-S CS 3882-085-035-S CS 3882-085-040-S CS 3882-085-045-S CS 3882-085-050-S CS 3882-085-055-S CS 3882-085-060-S CS 3882-100-045-S CS 3882-100-050-S CS 3882-100-055-S CS 3882-100-060-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000094QF: CS 3883-045-025-S CS 3883-045-030-S CS 3883-045-035-S CS 3883-045-040-S CS 3883-045-045-S CS 3883-045-050-S CS 3883-055-025-S CS 3883-055-030-S CS 3883-055-035-S CS 3883-055-040-S CS 3883-055-045-S CS 3883-055-050-S CS 3883-055-055-S CS 3883-065-030-S CS 3883-065-035-S CS 3883-065-040-S CS 3883-065-045-S CS 3883-065-050-S CS 3883-065-055-S CS 3883-065-060-S CS 3883-075-035-S CS 3883-075-040-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3883-075-045-S CS 3883-075-050-S CS 3883-075-055-S CS 3883-075-060-S CS 3883-085-035-S CS 3883-085-040-S CS 3883-085-045-S CS 3883-085-050-S CS 3883-085-055-S CS 3883-085-060-S CS 3883-100-045-S CS 3883-100-050-S CS 3883-100-055-S CS 3883-100-060-S			
4052536000095QH: CS 3884-045-025-S CS 3884-045-030-S CS 3884-045-035-S CS 3884-045-040-S CS 3884-045-045-S CS 3884-045-050-S CS 3884-055-025-S CS 3884-055-030-S CS 3884-055-035-S CS 3884-055-040-S CS 3884-055-045-S CS 3884-055-050-S CS 3884-055-055-S CS 3884-065-030-S CS 3884-065-035-S CS 3884-065-040-S CS 3884-065-045-S CS 3884-065-050-S CS 3884-065-055-S CS 3884-065-060-S CS 3884-075-035-S CS 3884-075-040-S CS 3884-075-045-S CS 3884-075-050-S CS 3884-075-055-S CS 3884-075-060-S CS 3884-085-035-S CS 3884-085-040-S CS 3884-085-045-S CS 3884-085-050-S CS 3884-085-055-S CS 3884-085-060-S CS 3884-100-045-S CS 3884-100-050-S CS 3884-100-055-S CS 3884-100-060-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000096QK: CS 3885-055-025-S CS 3885-055-030-S CS 3885-055-035-S CS 3885-055-040-S CS 3885-055-045-S CS 3885-055-050-S CS 3885-055-055-S CS 3885-065-030-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3885-065-035-S CS 3885-065-040-S CS 3885-065-045-S CS 3885-065-050-S CS 3885-065-055-S CS 3885-065-060-S CS 3885-075-035-S CS 3885-075-040-S CS 3885-075-045-S CS 3885-075-050-S CS 3885-075-055-S CS 3885-075-060-S CS 3885-085-035-S CS 3885-085-040-S CS 3885-085-045-S CS 3885-085-050-S CS 3885-085-055-S CS 3885-085-060-S			
4052536000097QM: CS 3802-045-025-S CS 3802-045-030-S CS 3802-045-035-S CS 3802-045-040-S CS 3802-045-045-S CS 3802-045-050-S CS 3802-055-025-S CS 3802-055-030-S CS 3802-055-035-S CS 3802-055-040-S CS 3802-055-045-S CS 3802-055-050-S CS 3802-055-055-S CS 3802-065-030-S CS 3802-065-035-S CS 3802-065-040-S CS 3802-065-045-S CS 3802-065-050-S CS 3802-065-055-S CS 3802-065-060-S CS 3802-075-035-S CS 3802-075-040-S CS 3802-075-045-S CS 3802-075-050-S CS 3802-075-055-S CS 3802-075-060-S CS 3802-085-035-S CS 3802-085-040-S CS 3802-085-045-S CS 3802-085-050-S CS 3802-085-055-S CS 3802-085-060-S CS 3802-100-045-S CS 3802-100-050-S CS 3802-100-055-S CS 3802-100-060-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000098QP: CS 3803-045-025-S CS 3803-045-030-S CS 3803-045-035-S CS 3803-045-040-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3803-045-045-S CS 3803-045-050-S CS 3803-055-025-S CS 3803-055-030-S CS 3803-055-035-S CS 3803-055-040-S CS 3803-055-045-S CS 3803-055-050-S CS 3803-055-055-S CS 3803-065-030-S CS 3803-065-035-S CS 3803-065-040-S CS 3803-065-045-S CS 3803-065-050-S CS 3803-065-055-S CS 3803-065-060-S CS 3803-075-035-S CS 3803-075-040-S CS 3803-075-045-S CS 3803-075-050-S CS 3803-075-055-S CS 3803-075-060-S CS 3803-085-035-S CS 3803-085-040-S CS 3803-085-045-S CS 3803-085-050-S CS 3803-085-055-S CS 3803-085-060-S CS 3803-100-045-S CS 3803-100-050-S CS 3803-100-055-S CS 3803-100-060-S			
4052536000099QR: CS 3804-045-025-S CS 3804-045-030-S CS 3804-045-035-S CS 3804-045-040-S CS 3804-045-045-S CS 3804-045-050-S CS 3804-055-025-S CS 3804-055-030-S CS 3804-055-035-S CS 3804-055-040-S CS 3804-055-045-S CS 3804-055-050-S CS 3804-055-055-S CS 3804-065-030-S CS 3804-065-035-S CS 3804-065-040-S CS 3804-065-045-S CS 3804-065-050-S CS 3804-065-055-S CS 3804-065-060-S CS 3804-075-035-S CS 3804-075-040-S CS 3804-075-045-S CS 3804-075-050-S CS 3804-075-055-S CS 3804-075-060-S CS 3804-085-035-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3804-085-040-S CS 3804-085-045-S CS 3804-085-050-S CS 3804-085-055-S CS 3804-085-060-S CS 3804-100-045-S CS 3804-100-050-S CS 3804-100-055-S CS 3804-100-060-S			
4052536000100PH: CS 3805-055-025-S CS 3805-055-030-S CS 3805-055-035-S CS 3805-055-040-S CS 3805-055-045-S CS 3805-055-050-S CS 3805-055-055-S CS 3805-065-030-S CS 3805-065-035-S CS 3805-065-040-S CS 3805-065-045-S CS 3805-065-050-S CS 3805-065-055-S CS 3805-065-060-S CS 3805-075-035-S CS 3805-075-040-S CS 3805-075-045-S CS 3805-075-050-S CS 3805-075-055-S CS 3805-075-060-S CS 3805-085-035-S CS 3805-085-040-S CS 3805-085-045-S CS 3805-085-050-S CS 3805-085-055-S CS 3805-085-060-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000101PK: CS 3812-01-015-S CS 3812-01-030-S CS 3812-01-060-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000105PT: CS 3902-35-10 CS 3902-35-12 CS 3902-35-14 CS 3902-35-16 CS 3902-35-18 CS 3902-35-20 CS 3902-35-22 CS 3902-35-24 CS 3902-35-26 CS 3902-35-28 CS 3903-40-10 CS 3903-40-12 CS 3903-40-14 CS 3903-40-16 CS 3903-40-18 CS 3903-40-20 CS 3904-40-26 CS 3904-40-28	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3904-40-30 CS 3904-40-32 CS 3904-40-34 CS 3904-40-36 CS 3904-40-38 CS 3904-40-40			
4052536000106PV: CS 3905-40-20 CS 3905-40-22 CS 3905-40-24 CS 3905-40-26 CS 3905-40-28 CS 3905-40-30 CS 3905-40-32 CS 3905-40-34 CS 3905-40-36 CS 3907-45-25 CS 3907-45-30 CS 3907-45-35 CS 3907-45-40 CS 3907-45-45 CS 3907-45-50 CS 3907-55-25 CS 3907-55-30 CS 3907-55-35 CS 3907-55-40 CS 3907-55-45 CS 3907-55-50 CS 3907-55-55	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000107PX: CS 3906-40-20 CS 3906-40-22 CS 3906-40-24 CS 3906-40-26 CS 3906-40-28 CS 3906-40-30 CS 3906-40-32 CS 3906-40-34 CS 3906-40-36 CS 3909-40-34 CS 3909-40-36 CS 3909-40-38 CS 3909-40-40 CS 3909-40-42 CS 3909-40-44 CS 3909-40-46 CS 3909-40-48 CS 3909-40-50	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000109Q3: CS 1400-34T CS 1400-36T CS 1400-38T CS 1400-40T CS 1400-42T CS 1400-44T CS 1400-46T CS 1400-48T CS 1400-50T CS 1401-20T	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 1401-22T CS 1401-24T CS 1401-26T CS 1401-28T CS 1401-30T CS 1401-32T CS 1401-34T CS 1401-36T CS 1401-38T			
4052536000115PW: CS 3913-06 CS 3913-07 CS 3913-08 CS 3913-09	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000134Q2: CS 3918-05-01 CS 3918-05-02 CS 3918-05-03	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000135Q4: CS 1409-01T	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000136Q6: CS 1411-3T CS 1413	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000137Q8: CS 1411-4T	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000138QA: CS 1412-2T CS 1412-4T	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000152Q4: CS 7171-04-S	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000174QE: CS 3801-01	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000175QG CS 3801-02	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000176QJ: CS 3807-030 CS 3807-035 CS 3807-040 CS 3807-045 CS 3807-050 CS 3807-055 CS 3807-060 CS 3807-065 CS 3807-070	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3807-075 CS 3807-080 CS 3807-085 CS 3807-090 CS 3807-095 CS 3807-100 CS 3807-110 CS 3807-120 CS 3807-132 CS 3807-144 CS 3807-156 CS 3807-168 CS 3807-180 CS 3807-200 CS 3807-300 CS 3807-400 CS 3807-500 CS 3808-030 CS 3808-035 CS 3808-040 CS 3808-045 CS 3808-050 CS 3808-055 CS 3808-060 CS 3808-065 CS 3808-070 CS 3808-075 CS 3808-080 CS 3808-085 CS 3808-090 CS 3808-095 CS 3808-100 CS 3808-110 CS 3808-120 CS 3808-132 CS 3808-144 CS 3808-156 CS 3808-168 CS 3808-180 CS 3808-200 CS 3808-300 CS 3808-400 CS 3808-500 CS 3809-030 CS 3809-035 CS 3809-040 CS 3809-045 CS 3809-050 CS 3809-055 CS 3809-060 CS 3809-065 CS 3809-070 CS 3809-075 CS 3809-080 CS 3812-400			
4052536000177QL: CS 3810-00 CS 3810-01 CS 3810-02 CS 3810-03	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3810-04 CS 3810-05 CS 3810-10 CS 3810-11 CS 3810-12 CS 3810-13 CS 3810-14			
4052536000178QN: CS 3812-01-015 CS 3812-01-030 CS 3812-01-060	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000186QM: CS 3901-01 CS 3917-12	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000187QP: CS 3913-04	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000188QR: CS 3910-01-025 CS 3910-01-030 CS 3910-01-035 CS 3910-01-040 CS 3910-01-045 CS 3910-01-050 CS 3910-01-055 CS 3910-01-060 CS 3910-01-070 CS 3910-01-080 CS 3910-01-090 CS 3910-01-100 CS 3910-01-110 CS 3910-01-120 CS 3910-020 CS 3910-025 CS 3910-030 CS 3910-035 CS 3910-040 CS 3910-045 CS 3910-050 CS 3910-055 CS 3910-060 CS 3910-065 CS 3910-070 CS 3910-075 CS 3910-080 CS 3910-085 CS 3910-090 CS 3910-095 CS 3910-100 CS 3910-120 CS 3910-140 CS 3910-160 CS 3910-200 CS 3910-240 CS 3911-240 CS 3911-400 CS 3912-200	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 7106-200 CS 7106-400			
4052536000189QT: CS 3913-10	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000190QC: CS 3912-240 CS 3913-40-03 CS 3913-40-04 CS 3913-40-05	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000191QE: CS 3913-55-06 CS 3913-55-08 CS 3913-55-10 CS 3913-55-12 CS 3913-55-14 CS 3913-55-16 CS 3914-50-06 CS 3914-50-08 CS 3914-50-10 CS 3914-50-12 CS 3914-50-14 CS 3914-50-16	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000192QG: CS 3913-05	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000193QJ: CS 3917-05 CS 3917-06 CS 3917-07 CS 3917-21 CS 3917-22 CS 3917-23	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000194QL: CS 3917-08 CS 3917-09 CS 3917-10	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000195QN: CS 3917-11	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000196QQ: CS 3919-02	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000197QS: CS 3918-01	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000198QU: CS 3918-02-02 CS 3918-02-03 CS 3918-06-07	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
CS 3918-06-09			
4052536000199QW: CS 3919-01 CS 7104-01	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000200PN: CS 1417-1T	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000201PQ: CS 1417-3T	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000202PS: CS 3913-11	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000203PU: CS 7104-12 CS 7104-16	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000204PW: CS 3918-06-11 CS 3918-06-14 CS 3918-06-17 CS 3918-06-20 CS 3918-07-07 CS 3918-07-09 CS 3918-07-11 CS 3918-07-14 CS 3918-07-17 CS 3918-07-20	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000211PT: CS 7170-075-040 CS 7170-075-050 CS 7170-075-060 CS 7170-075-070 CS 7170-075-080 CS 7170-085-060 CS 7170-085-070 CS 7170-085-080 CS 7170-085-090 CS 7170-085-100 CS 7170-085-110 CS 7170-085-120 CS 7170-100-080 CS 7170-100-090 CS 7170-100-100 CS 7170-100-110 CS 7170-100-120 CS 7170-100-130 CS 7170-100-140	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000212PV: CS 7171-06-01 CS 7171-06-02 CS 7171-06-03	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
4052536000213PX: CS 7171-01	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000214PZ: CS 7171-02	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000215Q3: CS 7171-03	☒ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123
4052536000218Q9: CS 3814-30-S	☒ Class IIb / Class IIb implantable (exempted)	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: MDR Article: CS 3814-30-S MDD Article: CS 3006-01	☒ Certification as follows: G1 011099 0060 Rev. 01, NB 0123

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
4052536000002PG: CS 2624 CS 3031-150 CS 3822-01 CS 3822-02 CS 3830-01 CS 3830-02 CS 3830-04 CS 3830-05 CS 3830-10 CS 3836 CS 3836-01 CS 3846 CS 3846-01 CS 3846-02 CS 3849 CS 3849-01 CS 3849-02 CS 3850-03	☒ Class Ir reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
4052536000003PJ: CS 7129-01 CS 7129-02 CS 7129-03 CS 7138 CS 7139 CS 7140 CS 7144 CS 7145 CS 7146 CS 7148	☒ Class Ir reusable surgical instruments	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: MDR Article: CS 7148 / MDD Article: CS 2828-20	☒ N/A - Device did not require a Notified Body certificate under Directives
4052536000004PL: CS 3020-01 CS 3024 CS 3825-01 CS 3825-02 CS 3825-03 CS 3826 CS 3826-01 CS 3827 CS 3827-01 CS 3831 CS 3831-01 CS 3832 CS 3832-01 CS 3833 CS 3833-01 CS 3834-01 CS 3834-02 CS 3834-03 CS 3835 CS 3835-01 CS 3847 CS 3847-01 CS 3848 CS 3851-01	☒ Class Ir reusable surgical instruments	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: MDR Article: CS 3848 / MDD Article: CS 2828-21	☒ 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
CS 3851-02 CS 3851-03 CS 3853-01 CS 3853-02 CS 3853-03 CS 3855 CS 3856-01 CS 3856-02 CS 3856-03 CS 3857 CS 3863 CS 3864 CS 5788 CS 7128-01 CS 7128-02 CS 7128-03 CS 7158-01 CS 7158-02 CS 8032-01 CS 8032-02 CS 8037 CS 8045 E02854 E03122 E03123 UT 1639-29			
4052536000005PN: CS 3018-04 CS 3018-05 CS 3018-06 CS 3018-07 CS 3033 CS 3041 CS 3041-01 CS 3041-02 CS 3041-03 CS 3041-04 CS 3041-05 CS 3820-01 CS 3820-02 CS 3820-03 CS 3820-04 CS 3821-01 CS 3821-02 CS 3823-100 CS 3824-045 CS 3824-045-01 CS 3824-045-02 CS 3824-055 CS 3824-055-01 CS 3824-055-02 CS 3824-065 CS 3824-065-01 CS 3824-065-02 CS 3824-075 CS 3824-075-01 CS 3824-075-02 CS 3824-085 CS 3824-085-01	☒ Class Ir reusable surgical instruments	☒ N/A	☒ 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
CS 3824-085-02 CS 3824-100 CS 3824-100-01 CS 3824-100-02 CS 3824-115-01 CS 3828-01 CS 3860 CS 3861 CS 7127-02 CS 7127-03 CS 7127-04 CS 7127-05 CS 7127-055 CS 7127-06 CS 7127-065 CS 7127-07 CS 7127-075 CS 7127-08 CS 7127-085 CS 7127-100 CS 7128-045 CS 7128-055 CS 7128-065 CS 7128-075 CS 7128-085 CS 7128-100 CS 7128-115 CS 7129-04 CS 7129-05 CS 7129-06 CS 7129-07 CS 7129-08 CS 8023 CS 8024 CS 8024-01 E02923 UL 8522-27 UL 8525-23 UL 8526-23 UL 8527-23 UL 8527-24			
4052536000006PQ: CS 3032-00 CS 3032-01 CS 3032-02 CS 3032-05 CS 3032-07 CS 3032-08 CS 3032-09 CS 3032-10 CS 3829 CS 3829-01 CS 3837 CS 3838-01 CS 3838-02 CS 3838-04 CS 3838-05 CS 3838-06 CS 3839	☒ Class Ir reusable surgical instruments	☒ N/A	☒ 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
CS 3840 CS 3841-01 CS 3841-03 CS 3841-04 CS 3841-10 CS 3843-20 CS 3843-21 CS 3843-30 CS 3844-01 CS 3844-02 CS 3844-03 CS 3844-04 CS 3844-05 CS 3844-06 CS 3845-01 CS 3845-02 CS 3852-01 CS 3852-02 CS 8038			
4052536000017PV: CS 2626-03 CS 2626-04 CS 2633-01 CS 2633-03 CS 2633-08 CS 2645-02 CS 2645-03 E02335-01 E02335-02	☒ Class Ir reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
4052536000019PZ: CS 2628 CS 2632 CS 2632-01 CS 2633-02 CS 2633-04 CS 2633-05 CS 2633-06 CS 2633-07 CS 2634-04 CS 2634-05 CS 2634-06 CS 2634-07 CS 2636 CS 2638 CS 2640 CS 2642 CS 2645-01 CS 2760-150 CS 2764-01 CS 2764-02 CS 2764-03	☒ Class Ir reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
4052536000020PJ: CS 2620-06 CS 2620-07 CS 2622 CS 2626-01 CS 2626-02 CS 2630-05	☒ Class Ir reusable surgical instruments	☒ N/A	☒ 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
CS 2630-06 CS 2630-07 E02172 E02362-02 E02362-03			
4052536000021PL: CS 2791 UT 1641-29	☒ Class Ir reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
4052536000022PN: CS 1450 CS 3923-01 CS 3923-02 CS 3924-410 CS 3924-530 CS 3926-04 CS 3926-05 CS 3927-04 CS 3928-04 CS 3928-05 CS 3929-02 CS 3929-04 CS 3929-05 CS 3929-06 CS 3945-01 CS 3950-05 CS 3950-06 CS 3950-07	☒ Class Ir reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
4052536000023PQ: CS 7150 CS 7152 CS 7154 CS 7155	☒ Class Ir reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
4052536000024PS: CS 1448 CS 1454 CS 1459 CS 1461 CS 1462-1 CS 1462-2 CS 1463-1 CS 1463-2 CS 1463-3 CS 1970-00-12 CS 1970-45-12 CS 3930 CS 3932-02 CS 3932-04 CS 3932-05 CS 3932-06 CS 3932-07 CS 3933 CS 3934 CS 3936-01 CS 3940-01 CS 3944-02 CS 3944-03 CS 3946	☒ Class Ir reusable surgical instruments	☒ N/A	☒ 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
CS 3954-01 CS 3954-03 CS 3955-02 CS 3957-01 CS 3961			
4052536000025PU: CS 1466 CS 3920-01 CS 3921-01 CS 3921-02 CS 3925-01 CS 3925-02 CS 3925-03 CS 3925-04 CS 3925-05 CS 3931 CS 3952-01 CS 3952-02	☒ Class Ir reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
4052536000026PW: CS 3937-03 CS 3937-04 CS 3938-03 CS 3938-04 CS 3938-05 CS 3938-06 CS 3938-07 CS 3938-08 CS 3938-09 CS 3939-01 CS 3941 CS 3942 CS 3943-03 CS 3943-04	☒ Class Ir reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
4052536000034PV: CS 7173-580 CS 7173-750 CS 7174-085-01 CS 7174-100-01 CS 7175-01 CS 7175-02 CS 7175-03 CS 7175-04 CS 7179	☒ Class Ir reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
4052536000035PX: CS 7174-02	☒ Class Ir reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
4052536000036PZ: CS 7128-04 CS 7128-05 CS 7177-01-01 CS 7177-01-02 CS 7177-01-03 CS 7177-02 CS 7177-10 CS 7177-11 CS 7178-01	☒ Class Ir reusable surgical instruments	☒ N/A	☒ 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
CS 7178-02 CS 7178-03			
4052536000037Q3: CS 7127-075-01 CS 7127-085-01 CS 7127-100-01 CS 7174-01 CS 7174-03 CS 7174-04 CS 7174-075 CS 7174-085 CS 7174-100 CS 7174-20 CS 7174-21 CS 7176-075 CS 7176-085 CS 7176-100	☒ Class Ir reusable surgical instruments	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-04-11	713316966 | 713315823	Initial issue