DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

KLS Martin SE & Co. KG

KLS Martin Platz 1
78532 Tuttlingen
Germany

Date: 2024.05.10

Notified Body Confirmation Letter
Reference: 1000176706

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has 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 following manufacturer:

KLS Martin SE & Co. KG

KLS Martin Platz 1
78532 Tuttlingen
Germany

Digitally signed by Gherman Irina
Date: 2024.10.02 13:54:33 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

SRN: DE-MF-000005551

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte 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 DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.
In the case of 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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, by the 20 Mar 2023 for the relevant devices. The transition timelines 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 (as amended by (EU) 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

On behalf of the Notified Body,

Viviana Indraccolo
Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
8100442 Maxium 40576051775Q	Class IIb	RF-surgery units Medical RF-surgery units for general and special applications Maxium (97, 106, 178)	210299 MR2 170776073 (NB 0297)
8100436 MD62 BUDI not assigned	Class IIb	RF-surgery units Medical RF-surgery units for general and special applications HF-Chirurgiegerät MD62 (106)	210299 MR2 170776073 (NB 0297)
8100511 TD-00136 40576051775Q	Class IIb	Argon Beamer Maxium Beamer (98)	210299 MR2 170776073 (NB 0297)
8100559 TD-00136 40576051785S 40576053485T	Class IIb	Argon Beamer MAXIUM SMART BEAM (143)	210299 MR2 170776073 (NB 0297)
8100496 TD-00133 40576053435H	Class IIb	RF-surgery units Medical RF-surgery units for general and special applications HF-Chirurgiegerät ME102) (104)	210299 MR2 170776073 (NB 0297)
8100449 TD-00129 40576053425F	Class IIb	RF-surgery units Medical RF-surgery units for general and special applications HF-Chirurgiegerät Minicutter (105)	210299 MR2 170776073 (NB 0297)
8100554 TD-00153 40576051785S	Class IIb	RF-surgery units Medical RF-surgery units for general and special applications MAXIUM SMART C (	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
8100591 TD-00153 40576051785S		142)	
HF-Handgriff steril, single use TD-00XXX not assigned BUDI not assigned	Class IIb	Handles for RF-surgery Handgriff semidisposable HANDGRIFF, 2 TASTEN, 3 PIN, 2,4MM, 3M, 90 (89, 90,171)	210299 MR2 170776073 (NB 0297)
HF-Handgriff steril, single use TD-00XXX not assigned BUDI not assigned	Class IIb	Handles for RF-surgery HF- Handgriff steril, inkl. aktive Elektrode und Rauchgas-absaugung, single use + HF-Handgriff steril, inkl. aktive Elektrode, single use, 90 (89, 91,172)	210299 MR2 170776073 (NB 0297)
8100492 TD-00132 40576053925W	Class IIb	Handles for RF-surgery MABS-Handgriff für starre Applikatoren (111, 112)	210299 MR2 170776073 (NB 0297)
8100522 TD-00139 405760539462	Class IIb	Electrodes MABS-Snare-Sonden (disposable) (110)	210299 MR2 170776073 (NB 0297)
8100514 TD-00138 40576053935Y	Class IIb	Electrodes MABS flexible Sonden (disposable) (108)	210299 MR2 170776073 (NB 0297)
8100492 TD-00132 40576053925W	Class IIb	Electrodes MABS-Beam-Elektroden (492)	210299 MR2 170776073 (NB 0297)
8100598 TD-00168 405760538867	Class IIb	Electrodes 86a Wiederverwendbare Neutralelektrode (92, 178)	210299 MR2 170776073 (NB 0297)
8100585 TD-00160	Class IIb	Electrodes Einmalneutralelectrode (96, 177)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
40576053505E			
8100593 TD-00167 40576053495V	Class IIb	Electrodes Aktiv Elektroden (93, 94, 95, 175)	210299 MR2 170776073 (NB 0297)
8100598 TD-00168 405760538867	Class IIb	Electrodes Wiederverwendbaren Neutralelektroden (178)	210299 MR2 170776073 (NB 0297)
8100507 TD00134 405760538765	Class IIb	Clamps, forceps MarClamp Bipolare Klemmen für die Gefäßversiegelung (114)	210299 MR2 170776073 (NB 0297)
8100530 TD-00144 40576053395S	Class IIb	Clamps, forceps MarSeal 10mm gebogenes Maulteil (115)	210299 MR2 170776073 (NB 0297)
8100529 TD-00143 40576053465P	Class IIb	Clamps, forceps Bipolare Pinzetten - Non-Stick red (120)	210299 MR2 170776073 (NB 0297)
8100529 TD-00143 40576053465P	Class IIb	Clamps, forceps Non Stick flush, bipolare Spülpinzetten (138)	210299 MR2 170776073 (NB 0297)
8100530 TD-00144 40576053395S	Class IIb	Clamps, forceps MarSeal slim (144)	210299 MR2 170776073 (NB 0297)
8100513 TD-00137 405760539564	Class IIb	Clamps, forceps MarLap - Bipolare Instrumente für die Laparoskopie (121)	210299 MR2 170776073 (NB 0297)
8100597 TD-00143 405760538969	Class IIb	Clamps, forceps Monopolare Pinzetten (118)	210299 MR2 170776073 (NB 0297)
8100597 TD-00143 405760538969	Class IIb	Clamps, forceps Bipolare Pinzetten (120)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
8100524 TD-00141 (Class I) 40576051805D	Class IIa	products for smoke evacuation MARVAC SMOKE EVACUATION SYSTEM (134)	210299 MR2 170776073 (NB 0297)
8100560 TD-00141 40576051795U	Class IIa	products for smoke evacuation maxium smart VAC (139)	210299 MR2 170776073 (NB 0297)
20-827-02 TD-00120 405760530457	Class III	UHP (prosthesis for wrist joint) Ulna Kopf Prothese (72, 189)	210299 MR2 170776073 (NB 0297)
20-826-02 TD-00119 40576052945V	Class III	Finger joint Capflex PIP (73, 190)	210299 MR2 170776073 (NB 0297)
14-006-06 TD-00058 405760550NF	Class IIb excluding Class IIb implantable non-WET	CranioXpand (156)	210299 MR2 170776073 (NB 0297)
21-833-02 TD-00082 40576051855P	Class IIa	Sterile scalpels / blades Sterile Skalpelle und Skalpellklingen (88, 166, 188)	210299 MR2 170776073 (NB 0297)
18-840-01 TD-00051 40576051365A	Class IIb	Drill bits OMF surgery Schraubendreher-Klingen(159)	210299 MR2 170776073 (NB 0297)
19-809-02 TD-00079 40576051455B (sterile) 40576051465D	Class IIa	Repositioning Instruments Repositionsinstrumente (162)	210299 MR2 170776073 (NB 0297)
18-840-01 TD-00051 40576051365A	Class IIa	Screwdriver blades Schraubendreher-Klingen (159)	210299 MR2 170776073 (NB 0297)
19-800-01	Class IIa	Bending Templates	210299 MR2 170776073

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
TD-00044 40576051385E 40576051395G		Biegeschablonen, unsteril (27, 164)	(NB 0297)
19-800-01 TD-00044 40576051375C	Class IIa	Bending Templates Biegeschablonen, steril (165)	210299 MR2 170776073 (NB 0297)
18-839-01 TD-00029 405760513456	Class IIa	Rotating cutting devices rotierende Schneidwerkzeuge, unsteril (160)	210299 MR2 170776073 (NB 0297)
21-846-01 TD-00111 40576053285M	Class I devices that qualify as re-usable surgical instruments	Rotating cutting devices rotierende Schneidwerkzeuge, unsteril (160)	210299 MR2 170776073 (NB 0297)
18-839-01 TD-00029 405760513354	Class IIa	Rotating cutting devices rotierende Schneidwerkzeuge, steril (161)	210299 MR2 170776073 (NB 0297)
18-839-01 TD-00029 405760513354	Class IIa	Rotating cutting devices IXOS Spiralbohrer (49)	210299 MR2 170776073 (NB 0297)
18-839-01 TD-00029 405760513354	Class IIa	Rotating cutting devices Recos Spiralbohrer (54)	210299 MR2 170776073 (NB 0297)
18-839-01 TD-00029 405760513354	Class IIa	Rotating cutting devices HBS 2 Spiralbohrer (60)	210299 MR2 170776073 (NB 0297)
18-839-01 TD-00029 405760513354	Class IIa	Rotating cutting devices Knochenbohrer (187)	210299 MR2 170776073 (NB 0297)
22-801-02 TD-00XXX (not assigned) VK M6 BUDI (not assigned)	Class IIb	Service Head Versorgungskonsole (3)	210299 MR2 170776073 (NB 0297)
97-008-03	Class IIa	Angled screwdriver	210299 MR2

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
TD-00055 40576051635D		Winkelschraubendreher (197)	170776073 (NB 0297)
37-000-02 TD-00083 40576051625B	Class IIa	Suction Units, Suction Cannulae, Irrigation Cannulae Saugkanülen (38, 155)	210299 MR2 170776073 (NB 0297)
37-000-02 TD-00083 40576051625B	Class IIa	Suction Units, Suction Cannulae, Irrigation Cannulae Insuflationskanülen (41)	210299 MR2 170776073 (NB 0297)
21-856-02 TD-00112 40576053335E	Class IIa	marTract marTract Retractor System (140)	210299 MR2 170776073 (NB 0297)
17-000-02 TD-00081 405760565NU	Class IIa	Wound spreading systems Wundspreizer (40)	210299 MR2 170776073 (NB 0297)
17-000-02 TD-00081 405760565NU	Class IIa	Wound spreading systems Rippensperrer (39)	210299 MR2 170776073 (NB 0297)
24-000-11 TD-00077 405760516159	Class I devices with a measuring function	N/A	N/A – Device did not require a Notified Body certificate under Directives
21-835-01 TD-00114 40576053535L	Class I devices with a measuring function	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00002 19-805-02 405760514153	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00012 14-006-05 405760553NM	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00016 19-806-01 405760514255	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
TD-00018 15-007-01 405760559NZ	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00052 19-804-01 40576051404Z	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00067 16-000-01 405760560NJ	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00068 17-000-01 405760563NQ	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00069 05-000-01 405760537NP	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00070 14-000-01 405760549NW	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00071 18-000-01 405760566NW	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00072 03-000-01 405760535NK	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00073 06-000-01 405760538NR	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00074 08-000-01 405760539NT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00076 20-000-01 40576051485H	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
TD-00093 21-830-01 40576053986A	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00096 21-843-01 40576053255F	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00101 21-845-01 40576053275K	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00111 21-846-01 40576053285M	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
TD-00115 21-836-01 40576053195L	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
8100549 TD-00152 405760531358	Class IIb	Clamps, forceps MARCLAMPCUT (135)	210299 MR2 170776073 (NB 0297)
8100549 TD-00152 405760531358	Class IIb	Clamps, forceps MARCLAMPCUT - sterile Klingen (136)	210299 MR2 170776073 (NB 0297)
8100523 TD-00140 40576052915P	Class IIb	Surgical laser units Limax 120 (NdYAG Laser) (124)	210299 MR2 170776073 (NB 0297)
8100523	Class IIb	Surgical laser units	210299 MR2

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
TD-00140 40576052915P		Limax 120 (NdYAG Laser)	170776073 (NB 0297)
8100533 BUDI not assigned	Class IIb	Laser contact probe Limax 60 (NdYAG Laser) (123)	210299 MR2 170776073 (NB 0297)
8100462 8100488 BUDI not assigned	Class IIb	Laser contact probe MCO 25plus, MCO 50plus (CO2 Laser) (122)	210299 MR2 170776073 (NB 0297)
8100533 TD-00XXX (not assigned) BUDI (not assigned)	Class IIb	Laser contact probe Limax 1064 (NdYAG Laser) (153)	210299 MR2 170776073 (NB 0297)
8100542 TD-00148 405760534NK	Class IIa	Adapter for laser fibres Faserhalter Flexpen 2.0 (154)	210299 MR2 170776073 (NB 0297)
8100509 TD-00135 405760539768	Class IIb	Connection fibres Gasgespülte Faser 400µm, universal (128)	210299 MR2 170776073 (NB 0297)
8100509 TD-00135 405760539768 8100512 1 TD-00145 405760529967	Class IIb	Connection fibres Bare Fiber universal, wiederverwendbar (126)	210299 MR2 170776073 (NB 0297)
8100558 TD-00145 405760539564 405760539666	Class IIb	Connection fibres TS Bare Fiber (150, 151)	210299 MR2 170776073 (NB 0297)
8100534 TD-00135 40576051945Q	Class IIb	Connection fibres VENEX 360° Faser mit Einführset (129)	210299 MR2 170776073 (NB 0297)
D-6-80536 TD-001XX (not assigned) BUDI (not assigned)	Class IIb	Connection fibres autoklavierbare Bare Fiber 400, 600 (127)	210299 MR2 170776073 (NB 0297)
8100537	Class IIb	Fibre optics	210299 MR2

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
TD-00146 40576052955X		Fokussierhandstück Limax (130)	170776073 (NB 0297)
8100544 TD-0045 40576051895X	Class IIb	Fibre optics FlexWave (149)	210299 MR2 170776073 (NB 0297)
8100462 8100488 TD-00XXX(not assigned)	Class IIb	Fibre optics Fokussierhandstück Scanner-Handstück (133)	210299 MR2 170776073 (NB 0297)
8100603 TD-00169 40576052965Z	Class IIa	Fibre optics VERBINDUNGSSCHLAUCH 25CM, LIMAX AN FASER (137)	210299 MR2 170776073 (NB 0297)
8-6-80463 TD-00XXX (not assigned) BUDI (not assigned)	Class IIb	Micromanipulator (132)	210299 MR2 170776073 (NB 0297)
8100568 TD-00XXX (not assigned) BUDI (not assigned)	Class IIb	Micromanipulator MicroPoint 2S (145)	210299 MR2 170776073 (NB 0297)
TD-00045 18-815-01, 18-815-03, 18-816-01 - Maxillary Distractors 405760586P4 405760590NT 405760592NX TD-00046 18-819-01 Cranial Distractor 40576051004M TD-00053 18-809-01, 18-811-01, 18-814-01, 18-810-05, 18-810-04 -	Class IIb excluding Class IIb implantable non-WET	Distractor Distraktor, intraoral (8)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Mandibular Distractors 405760571NP 405760572NR 405760573NT 405760576NZ 405760584NY TD-00087 18-821-01, 18-821-02 - Midface Distractors 40576051054X 40576051064Z TD-00088 18-813-01 - Mandibular Transversal Distraction 405760582NU TD-00095 18-808-01; 18-818-01 - Alveolar Distractors 405760568P2 405760598PB TD-00108 18-812-03, 18-812-01 - Mandibular Transport Distractors 405760578P5 405760580NQ			
TD-00021 18-817-01, 18-817-02 - Maxillary Transversal Distractors 405760594P3 405760593NZ 405760596P7	Class IIb excluding Class IIb implantable non-WET	Distractor Distraktor, extraoral (9)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
TD-00034 18-823-01 Activator 405760510957 TD-00035 18-820-01 RED Distractors 40576051014P TD-00036 18-820-02, 18-820-03 External Distractors 40576051024R 40576051034T TD-00098 18-824-01 – Fixators 40576051104Q TD-00098 18-824-02 - Fixators 40576051114S			
TD-00097 18-822-01 Extremity Distractors 405760510753	Class IIb excluding Class IIb implantable non-WET	Distractor Distraktor, Extremitäten (10)	210299 MR2 170776073 (NB 0297)
TD-00046 18-819-01 Cranial Distractor 40576051004M	Class IIb excluding Class IIb implantable non-WET	Distractor Dr. Arnaud Cranial Distractor (12)	210299 MR2 170776073 (NB 0297)
TD-00028 18-835-02 405760513252	Class III	Condylar implant Gelenkkopf-Aufsatz, unsteril (33)	210299 MR2 170776073 (NB 0297)
TD-00028 18-835-02 40576051314Y	Class III	Condylar implant Gelenkkopf-Aufsatz, steril	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
		(34)	
TD-00057 18-832-01 MMF Screws 405760512759 TD-00021 18-817-01, 18-817-02 - Maxillary Transversal Distractors 405760594P3 405760593NZ 405760596P7 TD-00035 18-820-01 RED Distractors 40576051014P TD-00036 18-820-02, 18-820-03 External Distractors 40576051024R 40576051034T	Class IIb excluding Class IIb implantable non-WET	Washers Unterlegscheibe (23)	210299 MR2 170776073 (NB 0297)
TD-00102 18-829-01 Mesh 40576051214V	Class IIb excluding Class IIb implantable non-WET	Meshes (for cranioplasty) Mesh, unsteril (21)	210299 MR2 170776073 (NB 0297)
TD-00102 18-829-01 Mesh 40576051204T (sterile)	Class IIb excluding Class IIb implantable non-WET	Meshes (for cranioplasty) Mesh, steril (22)	210299 MR2 170776073 (NB 0297)
TD-00102 18-825-01 1.0 Screws and Plates 40576051134W TD-00102 18-826-01 1.5 Screws and Plates	Class IIb excluding Class IIb implantable non-WET	Bone plates Platten, unsteril (14)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
405760511552 TD-00102 18-827-01 2.0-2.3 Screws and Plates 405760511756 TD-00102 18-828-01 2.7 Screws and Plates 40576051195A 21-861-01 Linos System 405760541NE 405760540NC TD-00102 18-830-01 Displacement plates 40576051234Z TD-00102 18-831-01 Burr hole cover 405760512555 TD-00102 18-834-01 Orbital Floor plates 40576051304W TD-00056 18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657 TD-00057 18-832-01 MMF Screws 405760512759		Linos Handfraktursystem (16)	

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
TD-00117 15-008-01 MMF Hybrid Arch bar 405760540258			
TD-00102 18-825-01 1.0 Screws and Plates 40576051124U (sterile) TD-00102 18-826-01 1.5 Screws and Plates 40576051144Y (sterile) TD-00102 18-827-01 2.0-2.3 Screws and Plates 405760511654 (sterile) TD-00102 18-828-01 2.7 Screws and Plates 405760511858 (sterile) 21-861-01 Linos System 405760541NE 405760540NC TD-00102 18-830-01 Displacement plates 40576051224X (Sterile) TD-00102 18-831-01 Burr hole cover 405760512453 (Sterile)	Class IIb excluding Class IIb implantable non-WET	Bone plates Platten, steril (15) Linos Handfraktursystem (16)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
TD-00102 18-834-01 Orbital Floor plates 40576051295D (sterile) TD-00056 18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657 TD-00057 18-832-01 MMF Screws 405760512657 (sterile) TD-00117 15-008-01 MMF Hybrid Arch bar 405760540258			
20-817-02 TD-00100 40576053065B 40576053014Z (sterile)	Class IIb excluding Class IIb implantable non-WET	Bone plates IXOS Platte (48,180)	210299 MR2 170776073 (NB 0297)
20-817-02 TD-00100 40576053065B 40576053014Z (sterile)	Class IIb excluding Class IIb implantable non-WET	Bone plates Recos Platte (52, 180)	210299 MR2 170776073 (NB 0297)
TD-00102 18-825-01 1.0 Screws and Plates 40576051134W 40576051124U (sterile) TD-00102 18-826-01 1.5 Screws and Plates 405760511552	Class IIb excluding Class IIb implantable non-WET	Bone screws Schrauben, unsteril (30)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
40576051144Y (sterile) TD-00102 18-827-01 2.0-2.3 Screws and Plates 405760511756 405760511654 (sterile) TD-00102 18-828-01 2.7 Screws and Plates 40576051195A 405760511858 (sterile) 21-861-01 Linos System 405760541NE 405760540NC TD-00102 18-830-01 Displacement plates 40576051234Z 40576051224X (Sterile) TD-00102 18-831-01 Burr hole cover 405760512555 405760512453 (Sterile) TD-00102 18-834-01 Orbital Floor plates 40576051304W 40576051295D (sterile) TD-00056		Linos Handfraktursystem (16)	

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657 TD-00057 18-832-01 MMF Screws 405760512759 405760512657 (sterile) TD-00117 15-008-01 MMF Hybrid Arch bar 405760540258			
TD-00102 18-825-01 1.0 Screws and Plates 40576051134W 40576051124U (sterile) TD-00102 18-826-01 1.5 Screws and Plates 405760511552 40576051144Y (sterile) TD-00102 18-827-01 2.0-2.3 Screws and Plates 405760511756 405760511654 (sterile) TD-00102 18-828-01 2.7 Screws and Plates 40576051195A 405760511858 (sterile)	Class IIb excluding Class IIb implantable non-WET	Bone screws Schrauben, steril (31)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
21-861-01 Linos System 405760541NE 405760540NC TD-00102 18-830-01 Displacement plates 40576051234Z 40576051224X (Sterile) TD-00102 18-831-01 Burr hole cover 405760512555 405760512453 (Sterile) TD-00102 18-834-01 Orbital Floor plates 40576051304W 40576051295D (sterile) TD-00056 18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657 TD-00057 18-832-01 MMF Screws 405760512759 405760512657 (sterile) TD-00117 15-008-01 MMF Hybrid Arch bar 405760540258		Linos Handfraktursystem (17)	

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
20-817-02 TD-00100 40576053065B 40576053014Z (sterile)	Class IIb excluding Class IIb implantable non-WET	Bone screws IXOS Schraube (47, 182)	210299 MR2 170776073 (NB 0297)
20-817-02 TD-00100 40576053065B 40576053014Z (sterile)	Class IIb excluding Class IIb implantable non-WET	Bone screws Recos Schraube (51, 182)	210299 MR2 170776073 (NB 0297)
20-825-02 TD-00085 405760530253 40576053075D (sterile)	Class IIb excluding Class IIb implantable non-WET	Bone screws HBS 2 Schrauben (59, 183)	210299 MR2 170776073 (NB 0297)
19-810-02 TD-00090 Pins & Wires 40576051475F	Class IIb excluding Class IIb implantable non-WET	Bone nails	210299 MR2 170776073 (NB 0297)
TD-00102 18-825-01 1.0 Screws and Plates 40576051134W 40576051124U (sterile) TD-00102 18-826-01 1.5 Screws and Plates 405760511552 40576051144Y (sterile) TD-00102 18-827-01 2.0-2.3 Screws and Plates 405760511756 405760511654 (sterile) TD-00102 18-828-01 2.7 Screws and Plates	Class IIb excluding Class IIb implantable non-WET	Fixation screws (25)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
40576051195A 405760511858 (sterile) 21-861-01 Linos System 405760541NE 405760540NC TD-00102 18-830-01 Displacement plates 40576051234Z 40576051224X (Sterile) TD-00102 18-831-01 Burr hole cover 405760512555 405760512453 (Sterile) TD-00102 18-834-01 Orbital Floor plates 40576051304W 40576051295D (sterile) TD-00056 18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657 TD-00057 18-832-01 MMF Screws 405760512759 405760512657 (sterile) TD-00117		Linos Handfraktursystem (17)	

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
15-008-01 MMF Hybrid Arch bar 405760540258			
TD-00102 18-825-01 1.0 Screws and Plates 40576051134W 40576051124U (sterile) TD-00102 18-826-01 1.5 Screws and Plates 405760511552 40576051144Y (sterile) TD-00102 18-827-01 2.0-2.3 Screws and Plates 405760511756 405760511654 (sterile) TD-00102 18-828-01 2.7 Screws and Plates 40576051195A 405760511858 (sterile) 21-861-01 Linos System 405760541NE 405760540NC TD-00102 18-830-01 Displacement plates 40576051234Z 40576051224X (Sterile) TD-00102	Class IIb excluding Class IIb implantable non-WET	Fixation screws (lug) (26) Linos Handfraktursystem (17)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
18-831-01 Burr hole cover 405760512555 405760512453 (Sterile) TD-00102 18-834-01 Orbital Floor plates 40576051304W 40576051295D (sterile) TD-00056 18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657 TD-00057 18-832-01 MMF Screws 405760512759 405760512657 (sterile) TD-00117 15-008-01 MMF Hybrid Arch bar 405760540258			
19-810-02 TD-00090 Pins & Wires 40576051475F	Class IIb excluding Class IIb implantable non-WET	Tantal wire (orthodontic)	210299 MR2 170776073 (NB 0297)
Bone clips	Class IIb excluding Class IIb implantable non-WET	Bone clips	210299 MR2 170776073 (NB 0297)
19-810-02 TD-00090 Pins & Wires 40576051475F	Class IIb excluding Class IIb implantable non-WET	Bone wire Osteosynthese Implantate Pins, Draht (Kirschnerdrähte)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
		(46, 185)	
21-822-01 TD-00048 405760554NP	Class IIb implantable non- WET device	marPOR Polyethylene Implants (157)	210299 MR2 170776073 (NB 0297)
19-810-02 TD-00090 Pins & Wires 40576051475F	Class IIb excluding Class IIb implantable non-WET	K-Wires K-Drähte (163)	210299 MR2 170776073 (NB 0297)
19-810-02 TD-00090 Pins & Wires 40576051475F	Class IIb excluding Class IIb implantable non-WET	K-Wires IXOS Führungsdrähte (50)	210299 MR2 170776073 (NB 0297)
19-810-02 TD-00090 Pins & Wires 40576051475F	Class IIb excluding Class IIb implantable non-WET	K-Wires RECOS Führungsdrähte (55)	210299 MR2 170776073 (NB 0297)
19-810-02 TD-00090 Pins & Wires 40576051475F	Class IIb excluding Class IIb implantable non-WET	K-Wires HBSA 2 Führungsdrähte (61)	210299 MR2 170776073 (NB 0297)
21-862-02 TD-00099 40576053545N	Class IIb excluding Class IIb implantable non-WET	Foot Osteosynthesis System (198, 199, 200, 167, 168, 169) Knochenplatten Fuß DTS-Mini, DTS kanüliert, Kopf anatom. abgeschrägt, Mini-Herbertschraube, DTS MCD- Knochenschrauben Fuß (167, 198)	210299 MR2 170776073 (NB 0297)
21-834-01 TD-00054 405760561NL	Class IIb excluding Class IIb implantable non-WET	Pelvis Fixation System Becken Fixation System (191, 192)	210299 MR2 170776073 (NB 0297)
21-824-01 TD-00050 40576052024W	Class III	Resorb X / xG / xC Plates Resorb X Platten (43, 194)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
			EG-Auslegungsprüf-bescheinigung 210299 MRA 170776239 (NB0297)
21-824-01 TD-00050 40576052024W	Class III	Resorb X / xG / xC Meshes Resorb X Meshes (42, 193)	210299 MR2 170776073 (NB 0297) EG-Auslegungsprüf-bescheinigung 210299 MRA 170776239 (NB0297)
21-824-01 TD-00050 40576052024W	Class III	Resorb X / xG / xC Foils Resorb X Meshes (42, 193)	210299 MR2 170776073 (NB 0297) EG-Auslegungsprüf-bescheinigung 210299 MRA 170776239 (NB0297)
21-824-01 TD-00050 40576052024W	Class III	Resorb X / xC Membranes Resorb X Meshes (42, 193)	210299 MR2 170776073 (NB 0297) EG-Auslegungsprüf-bescheinigung 210299 MRA 170776239 (NB0297)
21-824-01 TD-00050 40576052024W	Class III	Resorb X / xG / xC 3D Implants Resorb X Platten (43, 194)	210299 MR2 170776073 (NB 0297) EG-Auslegungsprüf-bescheinigung 210299 MRA 170776239 (NB0297)
21-824-01 TD-00050 40576052024W	Class III	Resorb X / xC Screws	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
		Resorb X Schrauben (44, 195)	EG-Auslegungsprüf-bescheinigung 210299 MRA 170776239 (NB0297)
21-824-01 TD-00050 40576052024W	Class III	Resorb X / xG / xC Pins (45, 196)	210299 MR2 170776073 (NB 0297) EG-Auslegungsprüf-bescheinigung 210299 MRA 170776239 (NB0297)
21-823-01 TD-00049 40576052935T	Class III	HBS2 Resorb Mg Screws (158)	210299 MR2 170776073 (NB 0297) EG- Auslegungsprüf-bescheinigung 548582 MRA 170774687 (NB0297)
19-810-02 TD-00090 Pins & Wires 40576051475F	Class IIb excluding Class IIb implantable non-WET	Guide pins (46, 185)	210299 MR2 170776073 (NB 0297)
19-810-02 TD-00090 Pins & Wires 40576051475F	Class IIb excluding Class IIb implantable non-WET	Guide wires (46, 185)	210299 MR2 170776073 (NB 0297)
21-825-01 TD-00080 40576053445K	Class IIa	SonicWeld Rx (basis device, handpieces) (35)	210299 MR2 170776073 (NB 0297)
21-825-01 TD-00080 405760546NQ 405760545NN (sterile)	Class IIa	SonicWeld Rx (sonotrodes) (36)	210299 MR2 170776073 (NB 0297)
21-829-01 TD-00014 405760543NJ	Class IIa	BOS driver (28)	210299 MR2 170776073 (NB 0297)

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
405760538663			
21-828-01 TD-00078 405760542NG	Class I devices placed on the market in sterile condition	BOS-Battery pack sterile (29)	210299 MR2 170776073 (NB 0297)
8100548 TD-00151 40576051835K	Class IIa	Clamps, forceps MarSeal5 - steriler Klingenträger (117)	210299 MR2 170776073 (NB 0297)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-11-01	10000138011	Initial issue
2024-05-10	1000176706	Three documentations changed to DNV Medcert (TD-00014, TD-00078, TD-00151) Instruments were added to the confirmation letter