

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

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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,

A handwritten signature in black ink, appearing to read 'V. Indraccolo'.

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) |

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|---|---|---|--|
| 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 Einmalneutralelektrode (96, 177) | 210299 MR2 170776073 (NB 0297) |

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|---|---|--|--|
| 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) |

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|---|---|--|--|
| 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 |

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|---|---|--|--|
| 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 |

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|---|---|--|--|
| 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 Insufflationskanülen (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 Rippensperrerr (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 |

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|---|---|--|--|
| 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 |

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|---|---|--|--|
| 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 |

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|---|---|--|--|
| 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 |

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|--|---|--|--|
| 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) |

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| <p>Mandibular Distractors</p> <p>405760571NP 405760572NR 405760573NT 405760576NZ 405760584NY</p> <p>TD-00087</p> <p>18-821-01, 18-821-02 - Midface Distractors</p> <p>40576051054X 40576051064Z</p> <p>TD-00088</p> <p>18-813-01 - Mandibular Transversal Distraction</p> <p>405760582NU</p> <p>TD-00095</p> <p>18-808-01; 18-818-01 - Alveolar Distractors</p> <p>405760568P2 405760598PB</p> <p>TD-00108</p> <p>18-812-03, 18-812-01 - Mandibular Transport Distractors</p> <p>405760578P5 405760580NQ</p> | | | |
| <p>TD-00021</p> <p>18-817-01, 18-817-02 - Maxillary Transversal Distractors</p> <p>405760594P3 405760593NZ 405760596P7</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Distractor</p> <p>Distraktor, extraoral (9)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |

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|---|---|--|--|
| <p>TD-00034 18-823-01 Activator 405760510957</p> <p>TD-00035 18-820-01 RED Distractors 40576051014P</p> <p>TD-00036 18-820-02, 18-820-03 External Distractors 40576051024R 40576051034T</p> <p>TD-00098 18-824-01 – Fixators 40576051104Q</p> <p>TD-00098 18-824-02 - Fixators 40576051114S</p> | | | |
| <p>TD-00097 18-822-01 Extremity Distractors 405760510753</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Distractor Distraktor, Extremitäten (10)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |
| <p>TD-00046 18-819-01 Cranial Distractor 40576051004M</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Distractor Dr. Arnaud Cranial Distractor (12)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |
| <p>TD-00028 18-835-02 405760513252</p> | <p>Class III</p> | <p>Condylar implant Gelenkkopf-Aufsatz, unsteril (33)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |
| <p>TD-00028 18-835-02 40576051314Y</p> | <p>Class III</p> | <p>Condylar implant Gelenkkopf-Aufsatz, steril</p> | <p>210299 MR2 170776073 (NB 0297)</p> |

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|---|---|--|--|
| <p>TD-00057 18-832-01 MMF Screws 405760512759</p> <p>TD-00021 18-817-01, 18-817-02 - Maxillary Transversal Distractors 405760594P3 405760593NZ 405760596P7</p> <p>TD-00035 18-820-01 RED Distractors 40576051014P</p> <p>TD-00036 18-820-02, 18-820-03 External Distractors 40576051024R 40576051034T</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>(34)</p> <p>Washers</p> <p>Unterlegscheibe (23)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |
| <p>TD-00102 18-829-01 Mesh 40576051214V</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Meshes (for cranioplasty)</p> <p>Mesh, unsteril (21)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |
| <p>TD-00102 18-829-01 Mesh 40576051204T (sterile)</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Meshes (for cranioplasty)</p> <p>Mesh, steril (22)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |
| <p>TD-00102 18-825-01 1.0 Screws and Plates 40576051134W</p> <p>TD-00102 18-826-01 1.5 Screws and Plates</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Bone plates</p> <p>Platten, unsteril (14)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |

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|---|---|--|--|
| <p>405760511552</p> <p>TD-00102 18-827-01 2.0-2.3 Screws and Plates 405760511756</p> | | | |
| <p>TD-00102 18-828-01 2.7 Screws and Plates 40576051195A</p> | | | |
| <p>21-861-01 Linos System 405760541NE 405760540NC</p> | | Linos Handfraktursystem | |
| <p>TD-00102 18-830-01 Displacement plates 40576051234Z</p> | | (16) | |
| <p>TD-00102 18-831-01 Burr hole cover 405760512555</p> | | | |
| <p>TD-00102 18-834-01 Orbital Floor plates 40576051304W</p> | | | |
| <p>TD-00056 18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657</p> | | | |
| <p>TD-00057 18-832-01 MMF Screws 405760512759</p> | | | |

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|---|---|--|--|---------------------------------|--|
| TD-00117 15-008-01 MMF Hybrid Arch bar 405760540258 | | | | | |
| TD-00102 18-825-01 1.0 Screws and Plates 40576051124U (sterile) | Class IIb excluding Class IIb implantable non-WET | Bone plates Platten, steril (15) | 210299 MR2 170776073 (NB 0297) | | |
| 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 | | | | Linos Handfraktursystem (16) | |
| TD-00102 18-830-01 Displacement plates 40576051224X (Sterile) | | | | | |
| TD-00102 18-831-01 Burr hole cover 405760512453 (Sterile) | | | | | |

| 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 |
|--|---|--|--|
| <p>TD-00102 18-834-01 Orbital Floor plates 40576051295D (sterile)</p> <p>TD-00056 18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657</p> <p>TD-00057 18-832-01 MMF Screws 405760512657 (sterile)</p> <p>TD-00117 15-008-01 MMF Hybrid Arch bar 405760540258</p> | | | |
| <p>20-817-02 TD-00100 40576053065B 40576053014Z (sterile)</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Bone plates IXOS Platte (48,180)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |
| <p>20-817-02 TD-00100 40576053065B 40576053014Z (sterile)</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Bone plates Recos Platte (52, 180)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |
| <p>TD-00102 18-825-01 1.0 Screws and Plates 40576051134W 40576051124U (sterile)</p> <p>TD-00102 18-826-01 1.5 Screws and Plates 405760511552</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Bone screws Schrauben, unsteril (30)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |

| 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) | | Linos Handfraktursystem (16) | |
| TD-00102 18-831-01 Burr hole cover 405760512555 405760512453 (Sterile) | | | |
| TD-00102 18-834-01 Orbital Floor plates 40576051304W 40576051295D (sterile) | | | |
| TD-00056 | | | |

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|---|---|--|--|
| <p>18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657</p> <p>TD-00057 18-832-01 MMF Screws 405760512759 405760512657 (sterile)</p> <p>TD-00117 15-008-01 MMF Hybrid Arch bar 405760540258</p> | | | |
| <p>TD-00102 18-825-01 1.0 Screws and Plates 40576051134W 40576051124U (sterile)</p> <p>TD-00102 18-826-01 1.5 Screws and Plates 405760511552 40576051144Y (sterile)</p> <p>TD-00102 18-827-01 2.0-2.3 Screws and Plates 405760511756 405760511654 (sterile)</p> <p>TD-00102 18-828-01 2.7 Screws and Plates 40576051195A 405760511858 (sterile)</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Bone screws Schrauben, steril (31)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |

| 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 |
|--|---|--|--|
| <p>21-861-01 Linus System 405760541NE 405760540NC</p> <p>TD-00102 18-830-01 Displacement plates 40576051234Z 40576051224X (Sterile)</p> <p>TD-00102 18-831-01 Burr hole cover 405760512555 405760512453 (Sterile)</p> <p>TD-00102 18-834-01 Orbital Floor plates 40576051304W 40576051295D (sterile)</p> <p>TD-00056 18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657</p> <p>TD-00057 18-832-01 MMF Screws 405760512759 405760512657 (sterile)</p> <p>TD-00117 15-008-01 MMF Hybrid Arch bar 405760540258</p> | | <p>Linus Handfraktursystem (17)</p> | |

| 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 |
|--|---|--|--|
| <p>40576051195A 405760511858 (sterile)</p> <p>21-861-01 Linor System 405760541NE 405760540NC</p> <p>TD-00102 18-830-01 Displacement plates 40576051234Z 40576051224X (Sterile)</p> <p>TD-00102 18-831-01 Burr hole cover 405760512555 405760512453 (Sterile)</p> <p>TD-00102 18-834-01 Orbital Floor plates 40576051304W 40576051295D (sterile)</p> <p>TD-00056 18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657</p> <p>TD-00057 18-832-01 MMF Screws 405760512759 405760512657 (sterile)</p> <p>TD-00117</p> | | <p>Linor Handfraktursystem (17)</p> | |

| 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) | Class IIb excluding Class IIb implantable non-WET | Fixation screws (lug) (26) | 210299 MR2 170776073 (NB 0297) |
| 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) | | Linos Handfraktursystem (17) | |
| TD-00102 | | | |

| 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 |
|---|---|--|--|
| <p>18-831-01 Burr hole cover 405760512555 405760512453 (Sterile)</p> <p>TD-00102 18-834-01 Orbital Floor plates 40576051304W 40576051295D (sterile)</p> <p>TD-00056 18-833-01 OrthoAnchor Plates and Screws 40576051285B 405760512657</p> <p>TD-00057 18-832-01 MMF Screws 405760512759 405760512657 (sterile)</p> <p>TD-00117 15-008-01 MMF Hybrid Arch bar 405760540258</p> | | | |
| <p>19-810-02 TD-00090 Pins & Wires 40576051475F</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Tantal wire (orthodontic)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |
| <p>Bone clips</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Bone clips</p> | <p>210299 MR2 170776073 (NB 0297)</p> |
| <p>19-810-02 TD-00090 Pins & Wires 40576051475F</p> | <p>Class IIb excluding Class IIb implantable non-WET</p> | <p>Bone wire Osteosynthese Implantate Pins, Draht (Kirschnerdrähte)</p> | <p>210299 MR2 170776073 (NB 0297)</p> |

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|---|---|---|--|
| | | (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) |

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|---|---|--|---|
| | | | EG-Auslegungsprüfbescheinigung 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-Auslegungsprüfbescheinigung 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-Auslegungsprüfbescheinigung 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-Auslegungsprüfbescheinigung 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-Auslegungsprüfbescheinigung 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-Auslegungsprüfbescheinigung 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-Auslegungsprüfbescheinigung 210299 MRA 170776239 (NB0297) |
| 21-823-01 TD-00049 40576052935T | Class III | HBS2 Resorb Mg Screws (158) | 210299 MR2 170776073 (NB 0297) EG- Auslegungsprüfbescheinigung 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) |

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|---|---|--|--|
| 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 |