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

Spiggle & Theis Medizintechnik GmbH

Burghof 14
51491 Overath
Germany

Date: 2024-05-23

Notified Body Confirmation Letter
Reference: 1000179861

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:

Spiggle & Theis Medizintechnik GmbH

Burghof 14
51491 Overath
Germany

SRN: DE-MF-000006647

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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

[redacted]

Melina Köhler
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
Ventilation Tubes made of Titanium Basic-UDI-DI: 4250381812A0101DE	Class IIb implantable non- WET device	N/A	056411 MR2 NB: 0297 170768616
Ventilation Tubes made of Silicone Basic-UDI-DI: 4250381812A0301DQ	Class IIb implantable non- WET device	N/A	056411 MR2 NB: 0297 170768616
Ventilation Tubes made of PTFE Basic-UDI_DI: 4250381812A0201DK	Class IIb implantable non- WET device	N/A	056411 MR2 NB: 0297 170768616
Partial Middle Ear Implants Basic-UDI-DI: 4250381810A0101CL	Class IIb implantable non- WET device	N/A	056411 MR2 NB: 0297 170768616
Total Middle Ear Implants Basic-UDI-DI: 4250381810A0101CL	Class IIb implantable non- WET device	N/A	056411 MR2 NB: 0297 170768616
Stapes Prostheses made of Platin/PTFE Basic-UDI-DI: 4250381811A0101CZ	Class IIb implantable non- WET device	Stapes Prostheses	056411 MR2 NB: 0297 170768616
Stapes Prostheses made of Nitinol/PTFE Basic-UDI-DI: 4250381811A0102D3	Class IIb implantable non- WET device	Stapes Prostheses	056411 MR2 NB: 0297 170768616
Stapes Prostheses made of Titanium Basic-UDI-DI: 4250381811A0201D6	Class IIb implantable non- WET device	Stapes Prostheses	056411 MR2 NB: 0297 170768616
Lid Implants made of Platinum/Iridium Basic-UDI-DI: 425038189A0101QY	Class IIb implantable non- WET device	N/A	056411 MR2 NB: 0297 170768616
Probing and Flushing Catheters (TubaClean®) 425038188B0101QW	Class IIa	N/A	056411 MR2 NB: 0297 170768616

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
Micro Drill- and Shaver-Systems and Accessories Basic-UDI-DI: 425038182A0101N5	Class IIa	N/A	056411 MR2 NB: 0297 170768616
HighSpeed Electronic Motor Basic-UDI-DI: 425038182A0102N7	Class IIa	Micro Drill- and Shaver-Systems and Accessories	056411 MR2 NB: 0297 170768616
LowSpeed Electronic Motor Basic-UDI-DI: 425038182A0103N9	Class IIa	Micro Drill- and Shaver-Systems and Accessories	056411 MR2 NB: 0297 170768616
HighSpeed Handpieces Basic-UDI-DI: 425038182B0101NG	Class IIa	Micro Drill- and Shaver-Systems and Accessories	056411 MR2 NB: 0297 170768616
LowSpeed Handpieces Basic-UDI-DI: 425038182B0201NM	Class IIa	Micro Drill- and Shaver-Systems and Accessories	056411 MR2 NB: 0297 170768616
Shaver Handpieces Basic-UDI-DI: 425038182B0301NS	Class IIa	Handpieces for Shaver-Systems	056411 MR2 NB: 0297 170768616
Rotary Instruments, unsterile, reusable Basic-UDI-DI: 425038183A0101NJ	Class IIa	Rotary Instruments	056411 MR2 NB: 0297 170768616
Rotary Instruments, sterile, single use Basic-UDI-DI: 425038183B0101NV	Class IIa	Rotary Instruments	056411 MR2 NB: 0297 170768616
Rotary Instruments, sterile, reusable Basic-UDI-DI: 425038183C0101P8	Class IIa	Rotary Instruments	056411 MR2 NB: 0297 170768616
Oscillating Instruments, (Shaverblades) Basic-UDI-DI: 425038184A0101NX	Class IIa	Oscillating Instruments	056411 MR2 NB: 0297 170768616
Irrigation-Sets Basic-UDI-DI: 425038187B0101QH	Class IIa	N/A	056411 MR2 NB: 0297 170768616

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
Suction and Irrigation Instruments including Suction Handles and Adaptors (reusable) Basic-UDI-DI: 425038185C0101Q2	Class IIa	Suction and Irrigation Instruments (reusable) Suction Handles and Adaptors (reusable)	056411 MR2 NB: 0297 170768616
Rigid Endoscopes Basic-UDI-DI: 425038186B0101Q4	Class IIa	Flexible and Rigid Endoscope Systems and Accessories	056411 MR2 NB: 0297 170768616
Single-Use Insertion Instruments (TubaInsert®) Basic-UDI-DI: 425038187D0101R7	Class I devices placed on the market in sterile condition	N/A	056411 MR2 NB: 0297 170768616
Single Use Suction Handle Basic-UDI-DI: 425038187C0101QU	Class IIa	N/A	056411 MR2 NB: 0297 170768616
ENT Single Use Suction tube for otology Basic-UDI-DI: 425038187C0201QZ	Class IIa	ENT Single Use Suction tube (otology, rhinology, laryngology)	056411 MR2 NB: 0297 170768616
ENT Single Use Suction tube for rhinology Basic-UDI-DI: 425038187C0301R6	Class IIa	ENT Single Use Suction tube (otology, rhinology, laryngology)	056411 MR2 NB: 0297 170768616
ENT Single Use Suction tube for laryngology Basic-UDI-DI: 425038187C0303RA	Class IIa	ENT Single Use Suction tube (otology, rhinology, laryngology)	056411 MR2 NB: 0297 170768616
Bipolar Forceps Basic-UDI-DI: 425038185D0201QJ	Class IIb excluding Class IIb implantable non-WET	HF-Instruments	056411 MR2 NB: 0297 170768616
Septal Buttons Basic-UDI-DI: 4250381813B0101E6	Class IIa	N/A	056411 MR2 NB: 0297 170768616
VoiceInject injection needles Basic-UDI-DI: 425038187H0201SQ	Class IIa	VoiceInject injection needle	056411 MR2 NB: 0297 170768616

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
Lipo harvesting-set Basic-UDI-DI: 425038187H0501T7	Class IIa	N/A	056411 MR2 NB: 0297 170768616
Lipo harvesting cannula Basic-UDI-DI: 425038187H0101SK	Class IIa	N/A	056411 MR2 NB: 0297 170768616
Inflation Devices and Accessories Basic-UDI-DI: 425038187A0101Q6	Class I devices placed on the market in sterile condition	N/A	056411 MR5 NB: 0297 170776252
Balloon Catheters for the Tuba Eustachii (TubaVent®, TubaVent® wide) Basic-UDI-DI: 425038188C0101R9	Class I devices placed on the market in sterile condition	Balloon Catheters for the Tuba Eustachii (TubaVent®)	056411 MR5 NB: 0297 170776252
Balloon Catheters for the Tuba Eustachii (TubaVent® short, TubaVent® short wide) Basic-UDI-DI: 425038188C0201RE	Class I devices placed on the market in sterile condition	Balloon Catheters for the Tuba Eustachii (TubaVent®)	056411 MR5 NB: 0297 170776252
Sterile Drapes for Technical Medical Devices Basic-UDI-DI: 4250381816C0101FQ	Class I devices placed on the market in sterile condition	Sterile Drapes for Microscopes and Technical Medical Devices	056411 MR5 NB: 0297 170776252
Sterile Drapes for Microscopes Basic-UDI-DI: 4250381816C0102FS	Class I devices placed on the market in sterile condition	Sterile Drapes for Microscopes and Technical Medical Devices	056411 MR5 NB: 0297 170776252
Septum Splints, with or without Respiratory Channel, made of Silicone Basic-UDI-DI: 4250381813C0101EH	Class I devices placed on the market in sterile condition	N/A	056411 MR5 NB: 0297 170776252
Septum Splints made of FEP Basic-UDI-DI: 4250381813C0102EK	Class I devices placed on the market in sterile condition	N/A	056411 MR5 NB: 0297 170776252
PVA-Products Basic-UDI-DI: 4250381816B0101FD	Class I devices placed on the market in sterile condition	Expanding Products suitable for the Absorption of Body	056411 MR5 NB: 0297 170776252

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
		Fluids and Secretions in deep Cavity Wounds, made of Polyvinylalcohol (PVA)	

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
Scissors Basic-UDI-DI: 425038185A0101PC	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Forceps (Tweezers) Basic-UDI-DI: 425038185A0201PH	Class I devices that qualify as re-usable surgical instruments	Forceps	N/A - Device did not require a Notified Body certificate under Directives
Forceps (Clamps) Basic-UDI-DI: 425038185A0301PN	Class I devices that qualify as re-usable surgical instruments	Clamps	N/A - Device did not require a Notified Body certificate under Directives
Elevators, Raspatories, Dissectors Basic-UDI-DI: 425038185A0401PT	Class I devices that qualify as re-usable surgical instruments	Raspatories Elevators Dissectors	N/A - Device did not require a Notified Body certificate under Directives
Knives, Adenoid curettes (ring cutter) Basic-UDI-DI: 425038185A0501PY Basic-UDI-DI (Roller Knives): 425038185A0502Q2	Class I devices that qualify as re-usable surgical instruments	Knives Score Instruments	N/A - Device did not require a Notified Body certificate under Directives
Rasps, Saws Basic-UDI-DI: 425038185A0601Q5	Class I devices that qualify as re-usable surgical instruments	Rasps	N/A - Device did not require a Notified Body

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
Basic-UDI-DI (Rasp Inserts): 425038185A0602Q7			certificate under Directives
Osteotomes, Chisels Basic-UDI-DI: 425038185A0701QA	Class I devices that qualify as re-usable surgical instruments	Osteotomes Chisels Gouges	N/A - Device did not require a Notified Body certificate under Directives
Hooks, Needles, Perforators Basic-UDI-DI: 425038185A0801QF Basic-UDI-DI (Tongue Forceps): 425038185A0802QH	Class I devices that qualify as re-usable surgical instruments	Hooks Perforators Micro Needles Suturing Needles Needles Skin Retractors Spreaders Retractors	N/A - Device did not require a Notified Body certificate under Directives
Titanium Microinstruments Basic-UDI-DI (Micro Hooks, Micro Needles): 425038185A0901QL Basic-UDI-DI (Micro Forceps): 425038185A0903QQ Basic-UDI-DI (Micro Ear Forceps): 425038185A0902QN	Class I devices that qualify as re-usable surgical instruments	Micro Hooks and Micro Needles made of Titanium Micro Forceps made of Titanium	N/A - Device did not require a Notified Body certificate under Directives
Probes, Cotton Carriers, Dilators Basic-UDI-DI: 425038185A1001PE Basic-UDI-DI (Cotton Carrier): 425038185A1002PG	Class I devices that qualify as re-usable surgical instruments	Probes (surgically invasive) Dilators	N/A - Device did not require a Notified Body certificate under Directives
Curettes, Spoons Basic-UDI-DI: 425038185A1101PK	Class I devices that qualify as re-usable surgical instruments	Spoons Abrasors (surgically invasive)	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
Injection needles, Trocars Basic-UDI-DI: 425038185A1201PQ	Class I devices that qualify as re-usable surgical instruments	Injection and Punction Needles Trocars	N/A - Device did not require a Notified Body certificate under Directives
Polyp snares, Tonsil snares Basic-UDI-DI: 425038185A1301PV Basic-UDI-DI (Loops): 425038185A1302PX Basic-UDI-DI (Tonsillotome Blade): 425038185A1303PZ	Class I devices that qualify as re-usable surgical instruments	Polypus Snares Guide Tubes Loops Stylets	N/A - Device did not require a Notified Body certificate under Directives
Punches Basic-UDI-DI: 425038185A1501Q7	Class I devices that qualify as re-usable surgical instruments	Punches and Malleus Nipper	N/A - Device did not require a Notified Body certificate under Directives
Cutting-, Pressure-, Holding forceps Basic-UDI-DI: 425038185A1601QC	Class I devices that qualify as re-usable surgical instruments	Forceps Bone Forceps Grasping Forceps Crimpers Nasal Forceps Nasal Dressing Forceps Conchotomes Rongeurs	N/A - Device did not require a Notified Body certificate under Directives
Biopsy forceps, Foreign body forceps Basic-UDI-DI: 425038185A1701QH Basic-UDI-DI (Forcep Tips): 425038185A1702QK	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Insertion instruments Basic-UDI-DI (Insertion instruments T-Tube): 425038185A1801QN	Class I devices that qualify as re-usable surgical instruments	Insertion Instrument for Cochlear Implants Inserting Instruments T-Tube Reference instruments (surgically invasive)	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
Basic-UDI-DI (Insertion Instruments Ventilation Tubes): 425038185A1802QQ Basic-UDI-DI (Insertion Instruments Cochlear Implants): 425038185A1803QS		Insertion Forceps for Ventilation Tubes	
Needle holders Basic-UDI-DI: 425038185A1901QT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Nasal, Tracheal Speculas Basic-UDI-DI: 425038185A2001PM	Class I devices that qualify as re-usable surgical instruments	Nose Specula	N/A - Device did not require a Notified Body certificate under Directives
Retractors Basic-UDI-DI: 425038185F0101R3	Class IIa	Retractors with ratchet	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
N/A	N/A	Initial issue