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

Peter Lazic GmbH

Immelmannweg 2

78532 Tuttlingen

2024-05-28

Notified Body Confirmation Letter

Reference: 1700775410

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 device

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:

Peter Lazic GmbH

Immelmannweg 2

78532 Tuttlingen

Germany

SRN: DE-MF-000005519

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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

Tim Unverzagt

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
Yasargil Aneurysmen Clip, permanent ***Yasargil Aneurysm Clip, permanent*** **42506037-3-0-AC01-L01-DQ**	III	Aneurysma clip system sterile and unsterile in the variants: Yasargil out of titanium and Phynox; Perneczky, L-Aneurysm-Clip and D-Clip out of titanium; each permanent and temporary III	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170771903 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Yasargil Aneurysmen Clip, temporär ***Yasargil Aneurysm Clip, temporary*** **42506037-3-0-AC01-L05-E4**	III	Aneurysma clip system sterile and unsterile in the variants: Yasargil out of titanium and Phynox; Perneczky, L-Aneurysm-Clip and D-Clip out of titanium; each permanent and temporary III	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170771903 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Yasargil Aneurysmen Clip Anlegezange ***Yasargil Aneurysm Clip Applying forceps*** **42506037-3-0-AC01-L09-EG**	III	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Perneczky Aneurysmen Clip2, permanent ***Perneczky Aneurysm Clip2, permanent***	III	Aneurysma clip system sterile and unsterile in the variants: Yasargil out of titanium and Phynox; Perneczky, L-Aneurysm-Clip	Certificate registration no.: 004182 MRA 004182 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
42506037-3-0-AC01-L02-DT		and D-Clip out of titanium; each permanent and temporary III	Certificate unique ID: 1700775410 170771903 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Perneczky Aneurysmen Clip2, temporär ***Perneczky Aneurysm Clip2, temporary*** **42506037-3-0-AC01-L06-E7**	III	Aneurysma clip system sterile and unsterile in the variants: Yasargil out of titanium and Phynox; Perneczky, L-Aneurysm-Clip and D-Clip out of titanium; each permanent and temporary III	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170771903 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Perneczky Aneursmen Clips 2 Anlegezange ***Perneczky Aneurysm Clip Applying forceps*** **42506037-3-0-AC01-L10-DS**	III	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
L-Aneurysm-Clip®, permanent ***L-Aneurysm-Clip®, permanent*** **42506037-3-0-AC01-L03-DW**	III	Aneurysma clip system sterile and unsterile in the variants: Yasargil out of titanium and Phynox; Perneczky, L-Aneurysm-Clip and D-Clip out of titanium; each permanent and temporary III	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170771903

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
			NB Identification: 0297 (DQS Medizinprodukte GmbH)
L-Aneurysm-Clip®, temporär ***L-Aneurysm-Clip®, temporary*** **42506037-3-0-AC01-L07-EA**	III	Aneurysma clip system sterile and unsterile in the variants: Yasargil out of titanium and Phynox; Perneczky, L-Aneurysm-Clip and D-Clip out of titanium; each permanent and temporary III	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170771903 NB Identification: 0297 (DQS Medizinprodukte GmbH)
L-Aneurysm-Clip® Anlegezange ***L-Aneurysm-Clip® Applying forceps*** **42506037-3-0-AC01-L11-DV**	III	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
D-Aneurysm-Clip®, permanent ***D-Aneurysm-Clip®, permanent*** **42506037-3-0-AC01-L04-DZ**	III	Aneurysma clip system sterile and unsterile in the variants: Yasargil out of titanium and Phynox; Perneczky, L-Aneurysm-Clip and D-Clip out of titanium; each permanent and temporary III	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170771903 NB Identification: 0297 (DQS Medizinprodukte GmbH)
D-Aneurysm-Clip®, temporär ***D-Aneurysm-Clip®, temporary***	III	Aneurysma clip system sterile and unsterile in the variants: Yasargil out of titanium and Phynox; Perneczky, L-Aneurysm-Clip	Certificate registration no.: 004182 MRA

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
42506037-3-0-AC01-L08-ED		and D-Clip out of titanium; each permanent and temporary III	004182 MR2 Certificate unique ID: 1700775410 170771903 NB Identification: 0297 (DQS Medizinprodukte GmbH)
D-Aneurysm-Clip® Anlegezange ***D-Aneurysm-Clip® Applying forceps*** **42506037-3-0-AC01-L12-DY**	III	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Spülsauger ***Suction Irrigation Device*** **42 506037-2A-0-SI01-A03-M3**	IIa	Suction Irrigation Device IIa	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Saugrohre ***Suction tube*** **42 506037-2A-0-SI01-A01-LV**	IIa	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)

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
Kanülen ***Cannula*** **42 506037-2A-0-SI01-A02-LY**	IIa	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Schere ***Scissors*** **42506037-1R-0-CR01-S01-77**	Ir wiederverwendbar	Class I instruments I and Neuro surgical instruments III	<u>Für Klasse I:</u> Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert <u>Für Klasse III:</u> Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Biopsie-Zange / Scharfe Mikrolöffel ***Biopsy forceps, sharp microspoon*** **42506037-1R-0-CR01-S02-7A**	Ir wiederverwendbar	Class I instruments I and Neuro surgical instruments III	<u>Für Klasse I:</u> Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert <u>Für Klasse III:</u> Certificate registration no.:

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
			004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Stanzen ***Punches*** **42506037-1R-0-CR01-S03-7D**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Rongeure ***Rongeur*** **42506037-1R-0-CR01-S04-7G**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Meißel ***Chisel*** **42506037-1R-0-CR01-S05-7K**	Ir wiederverwendbar	Class I instruments I and Neuro surgical instruments III	<u>Für Klasse I:</u> Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert <u>Für Klasse III:</u> Certificate registration no.: 004182 MRA

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
			004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Messer ***Knife*** **42506037-1R-0-CR01-S06-7N**	Ir wiederverwendbar	Neuro surgical instruments III	Certificate registration no.: 004182 MRA Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Löffel / Küretten ***Spoon / Curettes*** **42506037-1R-0-CR01-S07-7R**	Ir wiederverwendbar	Class I instruments I Und Neuro surgical instruments III	<u>Für Klasse I:</u> Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert <u>Für Klasse III:</u> Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)

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
Dissektor / Enukleator / Raspiratorium ***Dissector / Enukleator / Raspatory*** **42506037-1R-0-CR01-S08-7U**	Ir wiederverwendbar	Neuro surgical instruments III	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Dissektorgriffe ***Dissector handle*** **42506037-1R-0-CR01-S09-7X**	Ir wiederverwendbar	Neuro surgical instruments III	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Biegehilfe ***Bending tool*** **42506037-1R-0-CR01-S10-79**	Ir wiederverwendbar	Neuro surgical instruments III	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Skalpellgriffe ***Scalpel handle***	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert

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
42506037-1R-0-CR01-S11-7C			Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Pinzette ***Forceps*** **42506037-1R-0-CR01-G01-4K**	Ir wiederverwendbar	Class I instruments I and Neuro surgical instruments III	Für Klasse I: Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert Für Klasse III: Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Nadelhalter ***Needle holder*** **42506037-1R-0-CR01-G02-4N**	Ir wiederverwendbar	Class I instruments I and Neuro surgical instruments III	Für Klasse I: Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert Für Klasse III: Certificate registration no.: 004182 MRA 004182 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
			Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Fasszange ***Grasping forceps*** **42506037-1R-0-CR01-G03-4R**	Ir wiederverwendbar	Class I instruments I and Neuro surgical instruments III	Für Klasse I: Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert Für Klasse III: Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Tupferzange ***Sponge forceps*** **42506037-1R-0-CR01-G04-4U**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Nerv-Approximator ***Nerve-approximator***	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert

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
42506037-1R-0-CR01-G05-4X			Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Ersatznadeln für Nerv-Approximator ***Spare needles for nerve-approximator*** **42506037-1R-0-CR01-G06-52**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Schlüssel für Approximatoren ***Key for approximators*** **42506037-1R-0-CR01-G07-55**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Gefäßclips ***Vessel clips*** **42506037-1R-0-CR01-L01-5N**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Approximatoren ***Approximators*** **42506037-1R-0-CR01-L02-5R**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert

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
			NB Identification: 0297 (DQS Medizinprodukte GmbH)
Bulldogklemmen ***Bulldog clamps*** **42506037-1R-0-CR01-L03-5U**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Arterienklemmen ***Haemostatic forceps*** **42506037-1R-0-CR01-L04-5X**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Kopfhautklemme ***Scalp clips*** **42506037-1R-0-CR01-L05-62**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Anlegeinstrumente ***Applying forceps*** **42506037-1R-0-CR01-L06-65**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Haken ***Hooks***	Ir wiederverwendbar	Neuro surgical instruments III	Certificate registration no.: 004182 MRA

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
42506037-1R-0-CR01-H01-4S			004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Elevatorium ***Elevator*** **42506037-1R-0-CR01-H02-4V**	Ir wiederverwendbar	Neuro surgical instruments III	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)
Dilatatoren ***Dilators*** **42506037-1R-0-CR01-H03-4Y**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Wundhaken ***Retractors*** **42506037-1R-0-CR01-H04-53**	Ir wiederverwendbar	Class I instruments I	Certificate registration no.: Selbst deklariert Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Wundspreizer	Ir wiederverwendbar	Class I instruments	Certificate registration no.: Selbst deklariert

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
Retractors **42506037-1R-0-CR01-H05-56**		I	Certificate unique ID: Selbst deklariert NB Identification: 0297 (DQS Medizinprodukte GmbH)
Spatel ***Spatula*** **42506037-1R-0-CR01-H06-59**	Ir wiederverwendbar	Neuro surgical instruments III	Certificate registration no.: 004182 MRA 004182 MR2 Certificate unique ID: 1700775410 170769156 NB Identification: 0297 (DQS Medizinprodukte GmbH)

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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-28	1700775410	Initial issue