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

Erbrich-Instrumente GmbH

Eugenstraße 33

78532 Tuttlingen

Germany

2024-07-09

Notified Body Confirmation Letter

Reference: 170776143 (516070 MR2)

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:

Erbrich-Instrumente GmbH

Eugenstraße 33

78532 Tuttlingen

Germany

SRN: DE-MF-000012726

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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
Kanüle, Absaugung 40512950000000001PAPC	Class IIa	Kanüle, Absaugung, Iia Cannulae, Aspirating, IIa	Certificate (516070 MR2, ID 170776143) NB 0297
Kanüle, Auge 4051295000000002PC	Class IIa	Kanüle, Auge, Iia Cannulae, Eye, IIa	Certificate (516070 MR2, ID 170776143) NB 0297
Kanüle, Fettabsaugung 4051295000000003PE	Class IIa	Kanüle, Fettabsaugung, Iia Cannulae, Liposuction, IIa	Certificate (516070 MR2, ID 170776143) NB 0297
Kanüle, Nasal 4051295000000004PG	Class IIa	Kanüle, Nasal, IIa Cannulae, Nasal, IIa	Certificate (516070 MR2, ID 170776143) NB 0297
Kanüle, Ohr 4051295000000005PJ	Class IIa	Kanüle, Ohr, Iia Cannulae, Ear, IIa	Certificate (516070 MR2, ID 170776143) NB 0297
Kanüle, Uterin 4051295000000006PL	Class IIa	Kanüle, Uterin, Iia Cannulae, Uterine, IIa	Certificate (516070 MR2, ID 170776143) NB 0297
Nadel, Bipopsie 4051295000000007PN	Class IIa	Nadel, Biopsie, Iia Needle, Biopsy, IIa	Certificate (516070 MR2, ID 170776143)

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 0297
Pinzetten **4051295000000039Q3**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Fasszangen **4051295000000010PB**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Arterienklemme **4051295000000001PA**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Gefäßklemmen **4051295000000012PF**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Wunhaken **4051295000000059Q9**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Wundspreizer **4051295000000058Q7**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Sonstige Sonden **4051295000000047Q2**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Sonstige Wundkaken **4051295000000049Q6**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Wundhaken Auge	Class I devices that qualify as re-usable	N/A	N/A - Device did not require a Notified

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
40512950000000057Q5	surgical instruments		Body certificate under Directives
Nadelhalter **40512950000000032PM**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Biopsiezangen **40512950000000004PG**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Sonstige Haken **40512950000000046PY**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Spinalstanze **40512950000000050PP**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Darmfasszangen **40512950000000007PN**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Darmklemmen **40512950000000008PQ**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Nierensteinzangen **40512950000000035PT**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Gallenblasenzange **40512950000000011PD**	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
Gewebezangen **40512950000000013PH**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Tupferzangen **40512950000000054PX**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Unterbindungsnadel **40512950000000055PZ**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Küretten Uterine **40512950000000024PN**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Instrumentenzange **40512950000000016PP**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Küretten, Orthopädie **40512950000000025PQ**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Sonstige Häkchen **40512950000000045PW**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Sonstige Stanzen **40512950000000048Q4**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Knochensägen **40512950000000021PG**	Class I devices that qualify as re-usable	N/A	N/A - Device did not require a Notified

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
	surgical instruments		Body certificate under Directives
Instrumentenzange 40512950000000016PP	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Elevatoren 40512950000000009PS	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Küretten, dental 40512950000000026PS	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Tonsillenschnürer 40512950000000053PV	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Tonsillenklemmen 40512950000000051PR	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Hohlmeisselzangen 40512950000000015PM	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Knochenhaltezangen 40512950000000018PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Instrumentenzange 40512950000000016PP	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
Orthopädische Meissel **4051295000000036PV**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Orthopädische Schere **4051295000000037PX**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Knochenmeissel **4051295000000019PV**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Nasenmeissel **4051295000000033PP**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Knochensplitterzange **4051295000000022PJ**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Knochenraspeln **4051295000000020PE**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Schere **4051295000000040PL**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Vaskularschere **4051295000000056Q3**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Gynäkologie Schere **4051295000000014PK**	Class I devices that qualify as re-usable	N/A	N/A - Device did not require a Notified

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
	surgical instruments		Body certificate under Directives
Nasenschere **40512950000000034PR**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Tonsillenschere **40512950000000052PT**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Irisscheren **40512950000000017PR**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Tonsillenschere **40512950000000052PT**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Sonstige Augenscheren **40512950000000042PQ**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Augenschere Kornea **40512950000000002PC**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Augenspatel **40512950000000003PE**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Sonstige Haken Ophthal **40512950000000043PS**	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
Sonstige Spatel Ophth **40512950000000044PU**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Bulldogklemmen **40512950000000006PL**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Pädiatrische Klemmen **40512950000000038PZ**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Bronchenklemme **40512950000000005PJ**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Skallpellgriffe **40512950000000041PN**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Messerskalpell **40512950000000031PK**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Messer **40512950000000029PY**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Meniskusmesser **40512950000000028PW**	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Knorpelfeilen **40512950000000023PL**	Class I devices that qualify as re-usable	N/A	N/A - Device did not require a Notified

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
	surgical instruments		Body certificate under Directives
Mehrzweckklemmen 40512950000000027PU	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
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-07-09	170776143	Initial issue