EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

RUDOLF

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1
78567 Fridingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Non-active intruments (MD 0106), Non-active orthopaedic implants (MD 0202) and Active surgical devices (MD 1104) according annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	492576 MR2
Certificate unique ID	170769709
Effective date	2020-04-14
Expiry date	2023-11-20
Frankfurt am Main	2020-04-14

Digitally signed by Ermicev Alexandr
Date: 2024.07.15 13:15:25 EEST
Reason: MoldSign Signature
Location: Moldova

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 492576 MR2
Certificate unique ID: 170769709
Effective date: 2020-04-14

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1
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Device family	Device	Class
	Suction / irrigation units for Minimally Invasive Surgery	IIa
	CO2 insufflators for laparoscopy and hysteroscopy	IIa
	Irrigation units for arthroscopy	IIa
	Rigid endoscopes for arthroscopy, cystoscopy, hysteroscopy, laparoscopy, nephroscopy, neuroendoscopy, otoscopy, resectoscopy, sinuscopy, thoracoscopy, ureterorenoscopy, ventriculoscopy, and microdisectomy	IIa
	Saw blades for bone surgery	IIa
	Self-retaining retractors	IIa
	Endoscope element, sheath / trocar	IIa
Implants for orthopedics and traumatology:	Drillwire, Kirschner	IIb
	Bone nails, Steinmann	IIb
HF generators and Instruments for Open and Minimally Invasive Surgery:	Electro surgical electrode holder	IIb
	Electro surgical return electrode	IIb
	Electro surgical biopsy forceps	IIb
	Electro surgical electrodes	IIb
	HF-electro surgical unit with foot switch	IIb
	Bipolar / monopolar scissors	IIb
	Bipolar / monopolar forceps	IIb
	Electro surgical suction tip	IIb
	Resectoscopes	IIb
	Endoscopic snares	IIb
	Retrieval baskets	IIb

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

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1
78567 Fridingen
Germany

Date: 2023.10.13

Notified Body Confirmation Letter
Reference: 1000140215

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:

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1
78567 Fridingen
Germany

SRN: DE-MF-000005515

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,

Hovsep Aro
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
Bone pins and wires 4049356TD-010GR	Class IIb excluding Class IIb implantable non-WET	**Implants for orthopedics and traumatology:** Kirschner Drill Wire Dril Wire Kirschner Drill Wire Bone Wire Steinmann Bone Nail Orthopaedic bone pin, non-bioabsorbable Orthopaedic bone wire	492576 MR2 ID # 170769709 NB 0297
Electrodes bipolar 4049356TD-085HQ, reusable	Class IIb excluding Class IIb implantable non-WET	**Instruments for Open and Minimally Invasive Surgery:** Bipolar scissors Bipolar forceps Open-surgery electrosurgical handpiece/electrode, bipolar	492576 MR2 ID # 170769709 NB 0297
Electrodes monopolar 4049356TD-090HH, reusable	Class IIb excluding Class IIb implantable non-WET	**Instruments for Open and Minimally Invasive Surgery:** HF Handle Lancet Electrode Ballpoint Electrode Knife Electrode Needle Electrode Open-surgery electrosurgical electrode, monopolar	492576 MR2 ID # 170769709 NB 0297
MIC instruments bipolar 4049356TD-170HG, reusable	Class IIb excluding Class IIb implantable non-WET	**Instruments for Open and Minimally Invasive Surgery:** Handle only, Bipolar Dissector Maryland curved Bipolar Inserts Scissor curved Grasping Forceps Bipolar Coagulation Scissor Endoscopic electrosurgical handpiece/electrode, bipolar	492576 MR2 ID # 170769709 NB 0297
MIC instruments monopolar 4049356TD-175HS, reusable	Class IIb excluding Class IIb implantable non-WET	**Instruments for Open and Minimally Invasive Surgery:** Ballpoint electrode	492576 MR2 ID # 170769709 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
		Biopsy forceps Bowel grasping forceps Flexible needle Electrode, flexible Button electrode Flexible loop electrode Grasping forceps Shaft for exchangeable tips Insert grasping forceps Endoscopic electrosurgical handpiece/electrode, monopolar	
Resectoscopes 4049356TD-230H9, reusable	Class IIb excluding Class IIb implantable non-WET	**Instruments for Open and Minimally Invasive Surgery:** Resectoscopes	492576 MR2 ID # 170769709 NB 0297
Endo sheath systems 4049356TD-105H5, reusable, reusable	Class IIa	Arthroscope Sheath Albarran Deflector Lithotripsy Sheath Cysto-Urethroscope Sheath Laser Cysto-Urethroscope Sheath Easyport Trocar Sleeve Hysteroscope Sheath Endoscope sheath Laparoscopic access cannula, reusable Endoscope assembly adaptor	492576 MR2 ID # 170769709 NB 0297
Suction & irrigation instruments 4049356TD-305HF, reusable	Class IIa	Suction/irrigation units for Minimally Invasive Surgery Eustachian catheter, single-use Spring-loaded pneumoperitoneum needle Surgical irrigation/ aspiration cannula, non-illuminating Surgical/emergency suction cannula, non-illuminating,	492576 MR2 ID # 170769709 NB 0297
Retractor self-retaining 4049356TD-240HC, reusable	Class IIa	Orthopaedic surgical distractor, internal Rib spreader Self-retaining surgical retractor	492576 MR2 ID # 170769709 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
		Surgical drill guide Surgical retraction system Surgical screwdriver	
Endoscopes 4049356TD-200GY, reusable	Class IIa	Arthroscope, Sinuscope, Uretero-Renoscope, Cystoscope, Hysteroscope, Hysteroscope, Laparoscope, Endoscope, Optical medical device procedural cover Otoscope, direct Otoscope, endoscopic Rigid arthroscope, reusable, Rigid bronchoscope, Rigid cystoscope, Rigid fibreoptic hysteroscope, Rigid fibreoptic neuroscope, Rigid optical laparoscope, Rigid pharyngoscope, Rigid rhinoscope, Rigid sinoscope, Rigid thoracoscope, Rigid ureterorenoscope, Ultrasonic lithotripsy system handpiece	492576 MR2 ID # 170769709 NB 0297

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
Calipers 4049356TD-035H9	Class I devices that qualify as re-usable surgical instruments	Ophtahlmic calliper Orthopeadic bone calliper	n/a class 1 under MDD
Chisels **4049356TD-047HG**	Class I devices that qualify as re-usable surgical instruments	Bone Awl, Orthopaedic chisel, Orthopaedic osteotome	n/a class 1 under MDD

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
Clamps **4049356TD-050H5**	Class I devices that qualify as re-usable surgical instruments	Surgical A/V-shaped microvessel clamp, Surgical bulldog clamp, Surgical penis clamp, Umbilical cord clip	n/a class 1 under MDD
Curettes 4049356TD-060H8	Class I devices that qualify as re-usable surgical instruments	Adenoid curette, Bone curette, Ear excavator, Gallstone scoop, General-purpose curette, Intrauterine curette, manual, Intrauterine scoop, Lens spoon, Open-surgery dissector, Ophthalmic curette, reusable, Periodontal curette	n/a class 1 under MDD
Elevators 4049356TD-095HT	Class I devices that qualify as re-usable surgical instruments	Bone lever/elevator, Dental root elevator, ENT elevator, Intraocular hook/ spatula/manipulator, Uterine elevator	n/a class 1 under MDD
Endo instruments 4049356TD-100GT	Class I devices that qualify as re-usable surgical instruments	Flexible endoscopic biopsy forceps, Flexible endoscopic stone-retrieval forceps, Rigid endoscopic biopsy forceps, Rigid endoscopic scissors, Rigid endoscopic tissue manipulation forceps	n/a class 1 under MDD
Trocar spikes and obturators 4049356TD-110GW	Class I devices that qualify as re-usable surgical instruments	Laparoscopic trocar blade, Orthopaedic trocar blade, Rigid endoscope obturator	n/a class 1 under MDD
Files and rasps 4049356TD-120GZ	Class I devices that qualify as re-usable surgical instruments	Assistive nail file/emery board, Bone file/rasp, manual, Bone-resection orthopaedic reamer, Manual endodontic file/rasp, Middle ear file/rasp, Nasal file/rasp	n/a class 1 under MDD

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
Forceps **4049356TD-135HE**	Class I devices that qualify as re-usable surgical instruments	Airway tube forceps, reusable, Bone holding forceps, Cast spreader, Clamp manipulation forceps, Dental dressing forceps Dressing/utility forceps, scissors-like, Dressing/utility forceps, tweezer-like, Medical tubing clip/clamp, non-calibrated, Muscle biopsy clamp, Nasal septum straightening forceps, Obstetrical forceps, Open-surgery biopsy forceps, Open-surgery ligation clip applier, Open-surgery stone-retrieval forceps, Sterilizer transfer forceps, Surgical clip remover, Surgical soft-tissue manipulation forceps, alligator, Surgical soft-tissue manipulation forceps, scissors-like, Towel clamp	n/a class 1 under MDD
Hooks and picks **4049356TD-150HA**	Class I devices that qualify as re-usable surgical instruments	Antrotome, Bone hook, Eye spud/needle, General-purpose absorbent tip applicator/swab, intauterine device removal hook, Middle ear pick, Myoma screw, Nerve/vessel retractor, Soft-tissue surgical hook, Suture knot pusher, Suturing needle, Tendon/ligament tunneller, Tissue pick,	n/a class 1 under MDD

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
		Vein stripper, Wire/ligature passer	
Mallets 4049356TD-160HD	Class I devices that qualify as re-usable surgical instruments	Manual Bone mill, Percussion hammer, manual, Surgical mallet	n/a class 1 under MDD
Manual surgical rotary handpieces 4049356TD-165HP	Class I devices that qualify as re-usable surgical instruments	Manual surgical rotary handpiece	n/a class 1 under MDD
Mouth gags 4049356TD-182HP	Class I devices that qualify as re-usable surgical instruments	Mouth gag, adjustable, Tongue depressor, surgical	n/a class 1 under MDD
Nail clippers 4049356TD-185HV	Class I devices that qualify as re-usable surgical instruments	Nail clippers	n/a class 1 under MDD
Snares 4049356TD-190HN	Class I devices that qualify as re-usable surgical instruments	Adenotome, Nasal snare, Tonsillectome	n/a class 1 under MDD
Needle holders 4049356TD-195HY	Class I devices that qualify as re-usable surgical instruments	Razor blade breaker/holder, Suturing Needle holder, reusable	n/a class 1 under MDD
Pliers 4049356TD-215HD	Class I devices that qualify as re-usable surgical instruments	Nail extracting forceps, Orthopaedic cerclage applier, Surgical flat-nosed pliers, Tooth extraction forceps, Wire holding/twisting forceps	n/a class 1 under MDD
Probes & dilators 4049356TD-220H6	Class I devices that qualify as re-usable surgical instruments	Arthroscopic probe, Common bile duct dilator, Endoscopic-access dilator ENT probe, Fistula probe, Fixed-diameter cervical dilator, Gastro-urological probe, Gauze packer, Lacrimal dilator, Nasal dilator, Tracheal surgery dilator, Urethral bougie, Uterine sound, Vaginal dilator,	n/a class 1 under MDD

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
		Vascular dilator, Vessel spreader	
Punches 4049356TD-225HG	Class I devices that qualify as re-usable surgical instruments	Aorta punch, Bone-coring punch, Craniofacial rongeur, Skin-coring punch, Middle ear malleus nipper, Orthopaedic joint/limb rongeur, Spinal rongeur	n/a class 1 under MDD
Retractors hand-held 4049356TD-235HK	Class I devices that qualify as re-usable surgical instruments	Hand-held surgical retractor	n/a class 1 under MDD
Saws, surgical 4049356TD-246HQ	Class I devices that qualify as re-usable surgical instruments	Manual surgical saw blade, flexible, Manual surgical saw, rigid	n/a class 1 under MDD
Scalpel knives reusable 4049356TD-250HF	Class I devices that qualify as re-usable surgical instruments	Amniotic membrane perforator, Amputation knife, Autopsy knife, Brain knife, Cartilage knife Cast/plaster knife, Corneal marker, Corneal trephine, Cut-throat razor, Dura mater knife, Ear knife, Meniscus knife, Myomatome, Ophthalmic knife, Orthopaedic knife, Periodontal knife, Razor blade, Scalpel blade, Scalpel handle, Scalpel, Tendon stripper, Tonsil knife	n/a class 1 under MDD
Scissors 4049356TD-255HR	Class I devices that qualify as re-usable surgical instruments	Bandage scissors, Dental collar/crown scissors, Dental surgical scissors, Ear Scissors, General-purpose surgical scissors, Gynaecological scissors,	n/a class 1 under MDD

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
		Intraocular scissors, conventional-hinge, Intraocular scissors, probe-like, Nail scissors, Nail splitting forceps, Nail splitting scissors, Nasal scissors, Ophthalmic suture scissors Rectal Scissors, Suture scissors, Tonsil scissors, Umbilical cord scissors, vascular scissors	
Shears and cutters 4049356TD-275HX	Class I devices that qualify as re-usable surgical instruments	Brain spatula, Dental spatula, General-purpose surgical spatula, Lung spatula, Middle ear spatula	n/a class 1 under MDD
Speculum 4049356TD-290HT	Class I devices that qualify as re-usable surgical instruments	Endotracheal tube guide, Eyelid speculum, Nasal speculum, Proctoscope, Rectal speculum, Self-retaining ear speculum, Vaginal speculum	n/a class 1 under MDD
Tweezers 4049356TD-325HM	Class I devices that qualify as re-usable surgical instruments	Surgical soft-tissue manipulation forceps, tweezers-like	n/a class 1 under MDD
Urethrotomes 4049356TD-330HE	Class I devices that qualify as re-usable surgical instruments	Urethrotome	n/a class 1 under MDD
Spatulas 4049356TD-285J2	Class I devices that qualify as re-usable surgical instruments	Brain spatula, Dental spatula, General-purpose surgical spatula, Lung spatula, Middle ear spatula	n/a class 1 under MDD

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-10-13	1000140215	Initial issue