EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

REDA Instrumente GmbH

Gänsäcker 34
78532 Tuttlingen
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:

Traumatological Implants and Instruments for HF-Surgery, Endoscopes and accessories 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.	070894 MR2
Certificate unique ID	170742825
Effective date	2019-03-18
Expiry date	2023-05-07
Frankfurt am Main	2019-03-18

Digitally signed by Iarovoi Petru
Date: 2020.05.26 10:54:55 EEST
Reason: MoldSign Signature
Location: Moldova

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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.: 070894 MR2
Certificate unique ID: 170742825
Effective date: 2019-03-18

REDA Instrumente GmbH

Gänsäcker 34
78532 Tuttlingen
Germany

Device family	Device	UMDNS	Class
Traumatological Implants	Bone screws	16-101	IIb
	Bone wires	16-104	IIb
Instrumente for HF-surgery	**Monopolary and Bipolary**		
	HF-Electrode	16-860	IIb
	HF-Adapters	11-494	IIb
	Electrode Holders	11-497	IIb
	Electrodes active, foot controlled	16-206	IIb
Endoscopes and accessories	Endoscopes	11-274	IIa
	Laparoscope	12-291	IIa
	Thoracoscope	14-047	IIa
	Cystoscope	17-145	IIa
	Uretorenoscope	17-690	IIa
	Nephroscope	15-290	IIa
	Arthroscope	10-198	IIa

This annex is only valid in connection with the above-mentioned certificate.

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

REDA Instrumente GmbH

Gänsäcker 34

78532 Tuttlingen

2023-06-30

Notified Body Confirmation Letter

Reference: 170742825

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:

REDA Instrumente GmbH

Gänsäcker 34

78532 Tuttlingen

Germany

SRN: DE-MF-000005592

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
Monopolar and bipolar instruments for HF surgery **4063058000001153M** **4063058000001433S**	Class IIb excluding Class IIb implantable non-WET	Monopolar and bipolar instruments for HF surgery	Certificate registration no. 070894 MR2 Certificate unique ID 170742825 (DQS MED 0297)
Bone Wires **4063058000001223J**	Class IIb excluding Class IIb implantable non-WET	Bone Wires	Certificate registration no. 070894 MR2 Certificate unique ID 170742825 (DQS MED 0297)
Endoscopic and laparoscopic devices and accessories	Class IIb excluding Class IIb implantable non-WET	Endoscopic and laparoscopic devices and accessories	Certificate registration no. 070894 MR2 Certificate unique ID 170742825 (DQS MED 0297)
Endoscopic suction tubes and accessories	Class IIb excluding Class IIb implantable non-WET	Endoscopic suction tubes and accessories	Certificate registration no. 070894 MR2 Certificate unique ID 170742825 (DQS MED 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
-	-	-	-
-	-	-	-
-	-	-	-

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-06-30	170742825	Initial issue
-	-	-
-	-	-

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

REDA Instrumente GmbH
Gänsäcker 34
78532 Tuttlingen

Frankfurt a. M. 05.05.2023

Confirmation letter to certification under Directive 93/42/EEC (certification holder: REDA Instrumente GmbH; certificate registration no.: 070894 MR2; ID: 170742825; effective date: 2019-03-18; expiry date: 2023-05-07)

To whom it may concern,

This letter confirms that:

- The certificate referred to above was issued by DQS Medizinprodukte GmbH under the requirements of the Medical Device Directive (93/42/EEC) (the "MDD"); and
- the certificate referred to covers the legacy device(s) specified below, (or covered the legacy devices at the time of its expiry); and
- the certificate referred to above has either expired by course of time (and was valid at the date of its expiry, it neither having been suspended nor withdrawn), or is to expire shortly (and remains valid at the date of this letter); and
- an application under the MDR for the devices specified below has been accepted and the contract with the manufacturer signed for devices specified below.
- With reference to Regulation 2023/607 of March 15th, 2023, as well as the corresponding Q&A of the European Commission EC certificate will remain in spite of the self-declaration from REDA Instrumente GmbH valid until 26th May 2024.

This letter is limited to covering the following devices only:

- Monopolary and bipolary instruments for HF-surgery (UMDNS: 16-860, 11-494, 11-497, 16-206): Application MDR accepted on 2022-12-12 (MDA 0312)
- Endoscopic and laparoscopic devices and accessories (UMDNS: 11-274, 12-291): Application MDR accepted on 2022-12-12 (MDN 1208)
- Traumological implants (bone wires; UMDNS: 16-104): Application MDR accepted on 2022-12-12 (MDN 1102)
- Endoscopic suction tubes and accessories: Application MDR accepted on 2022-12-12 (MDA 0312)

Yours sincerely,

p.p.

DQS Medizinprodukte GmbH

EU Quality Management Certificate

This is to certify that the company

REDA Instrumente GmbH

Gänsäcker 34
78532 Tuttlingen
Germany

SRN: DE-MF-000005592

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

For placing of devices of class IIa, IIb or III listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	070894 MDR2017Q
Certificate ID	170782209
Effective date	2023-03-10
Expiry date	2028-03-09
Frankfurt am Main,	2023-03-10

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 5.0

Annex to EU Quality Management Certificate
SRN of Manufacturer:DE-MF-000005592
Certificate ID: 170782209

Device categories covered by this certificate:

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Risk classification:	Ir
Intended purpose:	Instruments and accessories are intended for multiple use and can be used individually for surgical use, or used as a component in a surgical set

Examinations and tests performed:
070894_A210346MED_01 dated 2023-01-27

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.
In the case of reusable surgical instruments, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing, as well as the related instructions for use.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a

CERTIFICATE

This is to certify that the company

REDA Instrumente GmbH

Gänsäcker 34
78532 Tuttlingen
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Manufacture Development and distribution of non-sterile surgical instruments, sterilization containers, ENT, dental, neuro- and ophthalmology instruments as well as non-sterile active and inactive medical products for endoscopy, orthopedics, HF electrodes and accessories.

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

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2018
ISO 13485 : 2016

Certificate registration no.	070894 MP2016
Certificate unique ID	1000158850
Effective date	2024-05-17
Expiry date	2027-05-16
Frankfurt am Main	2024-05-13

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

DQS IS A MEMBER OF
IQNET

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, info-med@dqs.de
The validity of this certificate can only be verified by the QR-code.

414_90e Version 3.0