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)

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