EU Quality Management Certificate

This is to certify that the company

Z-Medical GmbH & Co. KG

Gänsäcker 38
78532 Tuttlingen
Germany

SRN: DE-MF-000005471

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.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	490224 MDR2017Q
Certificate ID	1000205070
Effective date	2024-11-21
Expiry date	2029-11-20
Frankfurt am Main,	2024-11-21

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

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Device categories and variants covered by this certificate:

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 the certification can only be verified by the QR-code.

420.90 Version 7.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005471
Certificate ID: 1000205070

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	**Spine Set**
Risk classification:	Ir
Basic-UDI-DI:	4057217SPINESETAB
Intended purpose:	Set of instruments for application of MIS Z / SZ-Pedicle screws and Z-Rods for fixation, reconstruction and fusion of vertebrae in the spinal region preferable percutaneously. The screws can only be used in non cervical spine region. Per segment 4 screws and 2 rods are necessary.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	**Screw driver**
Risk classification:	Ir
Basic-UDI-DI:	4057217SCREWDRIVERXW
Intended purpose:	The screwdriver is designed for bringing in various implants with the help of the associated handle.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	**Probe Navigator**
Risk classification:	Ir
Basic-UDI-DI:	4057217PROBENAVIGATORX
Intended purpose:	The Z-Medical Probe Navigator is used as an aid for the pick-up and fixation of intraoperative miniature doppler probes (16MHz). For safe and optimal placement on the blood vessel during a surgical procedure.

Examinations and tests performed:
490224_A210805MED-01_dated 2023-03-24
490224_A210805MED_Wirbelsäulen Set dated 2024-10-01

Further conditions for or limitations to the validity of the certificate:
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