EU Quality Management Certificate

This is to certify that the company

PRO-MED INSTRUMENTE GMBH

PRO - MED Instrumente GmbH

Gänsäcker 9
78532 Tuttlingen
Germany

SRN: DE-MF-000005532

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.	057707 MDR2017Q
Certificate ID	1000269453
Effective date	2025-12-18
Expiry date	2030-08-13
Frankfurt am Main,	2025-12-18

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

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005532
Certificate ID: 1000269453

Device categories and variants covered by this certificate:

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SURGICAL SPOON, Ablating
Risk classification:	1r
Basic-UDI-DI:	4061706-0021-0000000002N7, 4061706-0010-0000000001KP
Intended purpose:	Instrument for scraping or ablating.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	ADENOTOME, Ablating
Risk classification:	1r
Basic-UDI-DI:	4061706-0021-0000000002N7
Intended purpose:	Instrument for scraping or ablating.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	FILE, Ablating
Risk classification:	1r
Basic-UDI-DI:	4061706-0021-0000000002N7
Intended purpose:	Instrument for scraping or ablating.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CURETTE, Ablating
Risk classification:	1r
Basic-UDI-DI:	4061706-0021-0000000002N7
Intended purpose:	Instrument for scraping or ablating.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	RASP, Ablating
Risk classification:	1r
Basic-UDI-DI:	4061706-0021-0000000002N7
Intended purpose:	Instrument for scraping or ablating.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SCRAPER, Ablating
Risk classification:	1r
Basic-UDI-DI:	4061706-0021-0000000002N7
Intended purpose:	Instrument for scraping or ablating.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SNARE INSTRUMENT, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0009-0000000003UX, 4061706-0023-0000000001QF
Intended purpose:	Instrument for separating.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	HOOK, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0028-0000000002WA, 4061706-0032-0000000001QK, 4061706-0046-0000000001WG
Intended purpose:	Instrument for lifting or positioning.

Device category:	MDN 1208 Non-active non-implantable instruments

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Product name:	DEPRESSOR, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0028-0000000002WA, 4061706-0032-0000000001QK
Intended purpose:	Instrument for lifting or positioning.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	ELEVATOR, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0028-0000000002WA
Intended purpose:	Instrument for lifting or positioning.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	LENS SLIDER, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0032-0000000001QK
Intended purpose:	Instrument for lifting or positioning.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	ELEVATOR, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0026-0000000002TY, 4061706-0028-0000000002WA
Intended purpose:	Instrument for lifting, ablating and dissecting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	ELEVATOR, Ablating
Risk classification:	1r
Basic-UDI-DI:	4061706-0026-0000000002TY
Intended purpose:	Instrument for lifting, ablating and dissecting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	ELEVATOR, DENTAL, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0026-0000000002TY
Intended purpose:	Instrument for lifting, ablating and dissecting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	APPLICATOR, CERCLAGE, ORTHOPEDIC, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0027-0000000001V3
Intended purpose:	Instrument for applying cerclage wire.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CATHETER, Suction rinsing draining
Risk classification:	1r
Basic-UDI-DI:	4061706-0029-0000000002XF
Intended purpose:	Instrument for passing fluids.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	NEEDLE, Puncturing
Risk classification:	1r
Basic-UDI-DI:	4061706-0045-0000000001VB, 4061706-0034-0000000001SV
Intended purpose:	Instrument for puncturing or perforating.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	PERFORATION INSTRUMENT, Puncturing
Risk classification:	1r
Basic-UDI-DI:	4061706-0045-0000000001VB
Intended purpose:	Instrument for puncturing or perforating.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	GOUGE PLIERS, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0011-0000000001LU, 4061706-0024-0000000001RL
Intended purpose:	Instrument for cutting and removal.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	TREPHINE, CUTTING, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0024-0000000001RL
Intended purpose:	Instrument for cutting and removal.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	TREPHINE, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0024-0000000001RL
Intended purpose:	Instrument for cutting and removal.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CHISEL, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0033-0000000001RQ
Intended purpose:	Instrument for cutting, inserting or compressing.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CHISEL, Introducing
Risk classification:	1r
Basic-UDI-DI:	4061706-0033-0000000001RQ
Intended purpose:	Instrument for cutting, inserting or compressing.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	OSTEOTOME, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0033-0000000001RQ, 4061706-0037-0000000001WC
Intended purpose:	Instrument for cutting, inserting or compressing.

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Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	GOUGE, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0033-0000000001RQ
Intended purpose:	Instrument for cutting, inserting or compressing.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	BRACKET, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0035-0000000001U2
Intended purpose:	Instrument for grasping and fixing.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SWAB CARRIER, ENDOSCOPY, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0038-0000000001XH
Intended purpose:	Instrument for grasping.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	DRILL, TURNING, Turning
Risk classification:	1r
Basic-UDI-DI:	4061706-0039-0000000001YN
Intended purpose:	Instrument for tightening.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	KNIFE HOLDER, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0011-0000000001LU
Intended purpose:	Instrument for holding a blade.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	FORCEPS, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0040-0000000001PJ, 4061706-0115-0000000001ST
Intended purpose:	Instrument for holding or cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CUTTING INSTRUMENT, BONE, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0040-0000000001PJ
Intended purpose:	Instrument for holding or cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	NEEDLE HOLDER, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0076-00000000012E
Intended purpose:	Instrument for holding and guiding needles or sutures.

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Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	THREAD GUIDE, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0076-00000000012E
Intended purpose:	Instrument for holding and guiding needles or sutures.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	TWEEZERS, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0049-000000000122, 4061706-0095-00000000023V
Intended purpose:	Instrument for holding, grasping or manipulating.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	FORCEPS, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0115-0000000001ST, 4061706-0119-0000000001XF
Intended purpose:	Instrument for holding, grasping or cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	FORCEPS, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0011-0000000001LU, 4061706-0115-0000000001ST
Intended purpose:	Instrument for holding, grasping or cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	EXTRACTOR, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0115-0000000001ST
Intended purpose:	Instrument for holding, grasping or cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	EXTRACTOR, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0115-0000000001ST
Intended purpose:	Instrument for holding, grasping or cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	ELEVATOR, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0115-0000000001ST
Intended purpose:	Instrument for holding, grasping or cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	ELEVATOR, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0115-0000000001ST
Intended purpose:	Instrument for holding, grasping or cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	FORCEPS, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0041-0000000002QR
Intended purpose:	Instrument for holding.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CLAMP, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0020-0000000001LY, 4061706-0116-0000000001TY
Intended purpose:	Instrument for clamping and holding.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CLAMP, BULLDOG, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0020-0000000001LY
Intended purpose:	Instrument for clamping, holding or closing vessels.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CLAMP, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0020-0000000001LY
Intended purpose:	Instrument for clamping, holding or closing vessels.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	APPROXIMATOR, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0020-0000000001LY
Intended purpose:	Instrument for clamping, holding or closing vessels.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	HAND DRILL/DRIVER, Turning
Risk classification:	1r
Basic-UDI-DI:	4061706-0044-0000000001U6
Intended purpose:	Instrument for manual drilling.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	DRILL, Turning
Risk classification:	1r
Basic-UDI-DI:	4061706-0044-0000000001U6
Intended purpose:	Instrument for manual drilling.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	HOOK, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0028-0000000002WA, 4061706-0046-0000000001WG, 4061706-0088-000000000365
Intended purpose:	Instrument for keeping wounds open.

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Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CLIP APPLICATOR, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0002-0000000002LS
Intended purpose:	Instrument for opening and closing clips.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SPATULA, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0042-0000000001RU, 4061706-0088-000000000365
Intended purpose:	Instrument for creating a field of vision or for application.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	TROCAR, PUNCTURING, Puncturing
Risk classification:	1r
Basic-UDI-DI:	4061706-0015-0000000001RG
Intended purpose:	Instrument for providing access or drainage of body fluids.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	TROCAR, Puncturing
Risk classification:	1r
Basic-UDI-DI:	4061706-0015-0000000001RG
Intended purpose:	Instrument for providing access or drainage of body fluids.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	FORCEPS, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0025-0000000001SR
Intended purpose:	Instrument for cutting or taking tissue samples.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SCISSORS, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0011-0000000001LU, 4061706-0043-0000000001SZ
Intended purpose:	Instrument for cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SCISSORS, NOSE, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0011-0000000001LU
Intended purpose:	Instrument for cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CUTTING PLIERS, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0011-0000000001LU
Intended purpose:	Instrument for cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	KNIFE, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0011-0000000001LU, 4061706-0043-0000000001SZ
Intended purpose:	Instrument for cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	FORCEPS, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0011-0000000001LU, 4061706-0024-0000000001RL
Intended purpose:	Instrument for cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	PUNCH, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0011-0000000001LU, 4061706-0043-0000000001SZ
Intended purpose:	Instrument for cutting.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SPREADER (EPICARDIAL), Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0068-00000000023H
Intended purpose:	Instrument for spreading tissue and creating a field of view.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SPREADER (ABDOMINAL RETRACTORS), Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0028-0000000002WA
Intended purpose:	Instrument for spreading tissue and creating a field of view.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SPREADER, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0068-00000000023H
Intended purpose:	Instrument for spreading tissue and creating a field of view.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SPREADER (RIB), Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0068-00000000023H
Intended purpose:	Instrument for spreading tissue and creating a field of view.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SPREADER (ENDOSPECULA), Examining
Risk classification:	1r
Basic-UDI-DI:	4061706-0121-0000000007PU
Intended purpose:	Instrument for spreading tissue and creating a field of view.

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Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CANNULA, Suction rinsing draining
Risk classification:	1r
Basic-UDI-DI:	4061706-0069-00000000014L
Intended purpose:	Instrument for rinsing or draining.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CANNULA, SUCTION, Suction rinsing draining
Risk classification:	1r
Basic-UDI-DI:	4061706-0069-00000000014L
Intended purpose:	Instrument for rinsing or draining.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	AWL, Puncturing
Risk classification:	1r
Basic-UDI-DI:	4061706-0070-0000000001TD
Intended purpose:	Instrument for piercing or widening holes.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	PROBE, Examining
Risk classification:	1r
Basic-UDI-DI:	4061706-0050-0000000001QT, 4061706-0104-0000000003QH
Intended purpose:	Instrument for examining.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	KNIFE, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0014-0000000001QB
Intended purpose:	Instrument for amputation.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	FORCEPS, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0075-000000002Z8
Intended purpose:	Instrument for use in forceps delivery or grasping.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	STRIPPER, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0077-00000000013K
Intended purpose:	Instrument for removal of veins or tendons.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	SCISSORS, Cutting
Risk classification:	1r
Basic-UDI-DI:	4061706-0051-0000000001RY
Intended purpose:	Instrument for enucleation.

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Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	DILATOR, Expanding
Risk classification:	1r
Basic-UDI-DI:	4061706-0098-00000000017A
Intended purpose:	Instrument for widening various anatomies.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	INJECTION, Suction rinsing draining
Risk classification:	1r
Basic-UDI-DI:	4061706-0016-0000000002SP
Intended purpose:	Instrument for injection or rinsing.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	LIGATOR, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0005-0000000002Q9
Intended purpose:	Instrument for interrupting blood flow.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	CLAMP, Holding
Risk classification:	1r
Basic-UDI-DI:	4061706-0105-0000000001RJ
Intended purpose:	Clamp for removing the male foreskin.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	GUIDE, Introducing
Risk classification:	1r
Basic-UDI-DI:	4061706-0108-0000000002V3
Intended purpose:	Medical device used as a guide for the insertion of other instruments.

Device category:	MDN 1208 Non-active non-implantable instruments
Product name:	FORCEPS, Accessory
Risk classification:	1r
Basic-UDI-DI:	4061706-0112-0000000001PC
Intended purpose:	Medical device for positioning.

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Examinations and tests performed:
057707_A213129MED_01 dated 2025-08-08
057707_A213129MED_02 Reusable cutting instruments (Class Ir) dated 2025-08-08

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
01	2025-08-14	1000208554	Addition/adjustment of products