



EU Quality Management Certificate



This is to certify that the company

MEDICON eG

Gänsäcker 15
78532 Tuttlingen
Germany

SRN: DE-MF-000005812

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.	31621332 MDR2017Q
Certificate ID	1000186533
Effective date	2025-03-06
Expiry date	2030-03-05
Frankfurt am Main,	2025-03-06



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

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director



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.



Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005812
Certificate ID: 1000186533

Device categories and variants covered by this certificate:

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Cutting instruments
Risk classification: Ir
Basic-UDI-DI: 4046826;B;R001;01;ag;2U
4046826;B;R001;02;ag;37
4046826;B;R001;03;ag;3J
4046826;B;R001;04;ag;3V
4046826;B;R001;05;ag;48
Intended purpose: An instrument (scissors, knives, needles/awls, cutting forceps and trocars) not used in conjunction with an active medical device and intended for a surgical procedure, the temporary use of which is to cut through tissue and bone during surgical procedures. The surgical instruments may only be used by surgeons with sufficient experience with regard to the purpose and function of the instruments in surgical procedures in clinics and surgeries. They are used on patients regardless of gender, age, weight, state of health or nationality. The surgical instrument can be reused after appropriate cleaning and sterilisation procedures have been carried out.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Holding instruments
Risk classification: Ir
Basic-UDI-DI: 4046826;B;R002;01;ah;3J
4046826;B;R002;02;ah;3V
4046826;B;R002;03;ah;48
4046826;B;R002;04;ah;4K
4046826;B;R002;05;ah;4W
4046826;B;R002;06;ah;59
Intended purpose: An instrument (forceps, tweezers, clamps, clips, laces) not used in conjunction with an active medical device and intended for a surgical procedure, the temporary use of which is to hold tissue and bone, in the case of needle holders to hold needles, during surgical procedures. The surgical instruments may only be used by surgeons with sufficient experience with regard to the purpose and function of the instruments during surgical procedures in clinics and surgeries. They are used on patients regardless of gender, age, weight, state of health or nationality. The surgical instrument can be reused after appropriate cleaning and sterilisation procedures have been carried out.



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Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Abrasive instruments
Risk classification: Ir
Basic-UDI-DI: 4046826;B;R003;01;ai;48
4046826;B;R003;02;ai;4K
4046826;B;R003;03;ai;4W
4046826;B;R003;04;ai;59
4046826;B;R003;05;ai;5L
4046826;B;R003;06;ai;5X

Intended purpose: An instrument (chisels, osteotomes, spoons, curettes, files, raspatories, saws, drills, milling cutters, thread cutters, punches, rongeurs) not used in conjunction with an active medical device and intended for a surgical procedure, whose temporary application is the abrasive removal of tissue and bone during surgical procedures. The surgical instruments may only be used by surgeons with sufficient experience with regard to the purpose and function of the instruments for surgical procedures in clinics and surgeries. They are used on patients regardless of gender, age, weight, state of health or nationality. The surgical instrument can be reused after appropriate cleaning and sterilisation procedures have been carried out.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Retaining, spreading and dilating instruments.
Risk classification: Ir
Basic-UDI-DI: 4046826;B;R004;01;aj;4W
4046826;B;R004;02;aj;59
4046826;B;R004;03;aj;5L
4046826;B;R004;04;aj;5X
4046826;B;R004;05;aj;6A
4046826;B;R004;06;aj;6M
4046826;B;R005;03;ak;6A

Intended purpose: An instrument (dilators, spreaders, retractors, contractors, retractors, dissectors, elevators, probes) not used in conjunction with an active medical device and intended for a surgical procedure, the temporary use of which is to remove, spread and dilate tissue and bone during surgical procedures. The surgical instruments may only be used by surgeons with sufficient experience with regard to the purpose and function of the instruments in surgical procedures in clinics and surgeries. They are used on patients regardless of gender, age, weight, state of health or nationality. The surgical instrument can be reused after appropriate cleaning and sterilisation procedures have been carried out.



Annex to EU Quality Management Certificate
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Certificate ID: 1000186533

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Application instruments
Risk classification: Ir
Basic-UDI-DI: 4046826;B;R005;01;ak;5L
4046826;B;R005;02;ak;5X
4046826;B;R005;03;ak;6A
4046826;B;R005;04;ak;6M
Intended purpose: An application instrument (forceps, templates, guides, introducers, tampers, plungers and holders) not used in conjunction with an active medical device and intended for a surgical procedure, the temporary use of which is bending, holding, transferring shapes and sizes and inserting implants and surgical instruments during surgical procedures. The surgical instruments may only be used by surgeons with sufficient experience with regard to the purpose and function of the application instruments during surgical procedures in clinics and surgeries. They may be used on patients regardless of gender, age, weight, state of health or nationality. The application instruments can be reused after appropriate cleaning and sterilisation procedures have been carried out.

Examinations and tests performed:

31621332_A215328MED_01 dated 2025-03-03

31621332_A215343MED_02 Application instruments dated 2025-03-04

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