



EU Quality Management Certificate



This is to certify that the company



Industriestrasse 12
9450 Altstätten
Switzerland

SRN: CH-MF-000026833

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.	364530 MDR2017Q
Certificate ID	1000264973
Effective date	2025-10-25
Expiry date	2029-02-12
Frankfurt am Main,	2025-10-25



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zflg.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: CH-MF-000026833
Certificate ID: 1000264973

Authorised Representative of the company:

Icotec Medical GmbH

In der Au 25
61440 Oberursel
Germany

SRN: DE-AR-000016837

Device categories and variants covered by this certificate:

Device category: **MDN 1102/A - Non-active rigid osteo- and orthopaedic implants**
Product name: VADER® Pedicle System
Risk classification: IIb Implant
Basic-UDI-DI: 764017255PSISCRBA00185, 764017255PSISCRTi001MY,
764017255PSIRODBA00188, 764017255PSIRODTi001N3,
764017255PSINUTSTi0014F, 764017255PSICONTi001H8,
764017255PSIRODBATi001P6
Intended purpose: The icotec Pedicle Systems are intended to provide immobilization and stabilization of spinal segments.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: VADER® Pedicle System Instruments
Risk classification: IIa
Basic-UDI-DI: 764017255iPSI0002AQ, 764017255iPSI0003AS, 764017255iPSI0004AU,
764017255iPSI0005AW, 764017255iPSI0007B2, 764017255iPSI0008B4,
764017255iPSI0009B6, 764017255iPSI0011AR, 764017255iPSI0012AT,
764017255iPSI0013AV, 764017255iPSI0018B7, 764017255iPSI0022AW,
764017255iPSI0023AY, 764017255iPSI0024B2, 764017255iPSI0026B6,
764017255iPSI0028BA, 764017255iPSI0029BC, 764017255iPSI0030AV,
764017255iPSI0031AX, 764017255iPSI0035B7, 764017255iPSI0036B9,
764017255iPSI0037BB, 764017255iPSI0038BD, 764017255iPSI0039BF,
764017255iPSI0041B2, 764017255iPSI0042B4, 764017255iPSI0043B6,
764017255iPSI0045BA, 764017255iPSI0046BC, 764017255iPSI0047BE,
764017255iPSI0048BG, 764017255iPSI0049BJ, 764017255iPSI0050B3,
764017255iPSI0051B5, 764017255iPSI0055BD, 764017255iPSI0056BF,
764017255iPSI0058BK, 764017255iPSI0059BM, 764017255iPSI0060B6,
764017255iPSI0061B8, 764017255iPSI0068BN, 764017255iPSI0001AN,
764017255iPSI0072BD, 764017255iNPSI0001XZ, 764017255iNPSI0002Y3,
764017255iNPSI0003Y5, 764017255iNPSI0007YD,
764017255iNPSI0005Y9
Intended purpose: Implantation and if required revision of icotec Pedicle System implant devices.



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Device category: **MDN 1102/A - Non-active rigid osteo- and orthopaedic implants**
Product name: KONG® VBR implants
Risk classification: III
Basic-UDI-DI: 76017255VBRTLBOBDA001EE, 76017255VBRTLEXTBA001TG, 76017255VBRTLSCRBA001PT, 76017255VBRTLPLABA001KW, 76017255VBRCBODBA001R4, 76017255VBRCLPLABA001WL, 76017255VBRCSRBA0012L

Intended purpose: The KONG®-C VBR System is intended to be used for stabilization and fusion of the cervical spine following vertebral corpectomy. The KONG®-C VBR System is intended to be used with supplemental spinal fixation systems.
The KONG®-TL VBR System is intended to be used for stabilization and fusion of the thoracolumbar spine following vertebral corpectomy. The KONG®-TL VBR System is intended to be used with supplemental spinal fixation systems.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: KONG®-C VBR and KONGR®-TL VBR Instruments
Risk classification: IIa
Basic-UDI-DI: 764017255iVBRC0001SU, 764017255iVBRC0002SW, 764017255iVBRC0003SY, 764017255iVBRC0004T2, 764017255iVBRC0005T4, 764017255iVBRC0006T6, 764017255iVBRC0007T8, 764017255iVBRC0009TC, 764017255iVBRC0010SV, 764017255iVBRTL0001XF, 764017255iVBRTL0002XH, 764017255iVBRTL0003XK, 764017255iVBRTL0004XM, 764017255iVBRTL0005XP, 764017255iVBRTL0008XV, 764017255iVBRTL0009XX, 764017255iVBRTL0010XG, 764017255iVBRTL0012XL, 764017255iVBRTL0014XQ, 764017255iVBRTL0016XU, 764017255iVBRTL0018XY, 764017255iVBRTL0019Y2

Intended purpose: The instruments are intended for short term use during surgeries for implantation and, if required, revision of icotec VBR System implant devices.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: icotec Anterior Cervical Plate Instruments
Risk classification: IIa
Basic-UDI-DI: 764017255iCPI00012J, 764017255iCPI00022L, 764017255iCPI00032N, 764017255iCPI00042Q, 764017255iCPI00052S, 764017255iCPI00072W, 764017255iCPI00082Y, 764017255iCPI000932, 764017255iCPI00102K, 764017255iCPI00112M, 764017255iCPI00122P, 764017255iCPI00132R

Intended purpose: The instruments are intended for short term use during surgeries for implantation and, if required, revision of icotec Anterior Cervical Plate implant devices.



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Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Cervical Cages Instruments
Risk classification: IIa
Basic-UDI-DI: 764017255iCSI00013R, 764017255iCSI00023T, 764017255iCSI00043X, 764017255iCSI00053Z
Intended purpose: The instruments are intended for short term use during surgeries for implantation and, if required, revision of icotec Cervical Cage implant devices.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Lumbar Cages Instruments
Risk classification: IIa
Basic-UDI-DI: 764017255iLCAGE000185, 764017255iLCAGE000287, 764017255iLCAGE00058D, 764017255iLCAGE00068F, 764017255iLCAGE00078H, 764017255iLCAGE00098M, 764017255iLCAGE001188, 764017255iLCAGE00148E
Intended purpose: The instruments are intended for short term use during surgeries for implantation and, if required, revision of icotec Lumbar Cage implant devices.

Examinations and tests performed:

364530_A212274MED dated 2023-04-21
364530_A214693MED VADER® Pedicle Systems Instruments dated 2025-01-31
364530_A216062MED Vader® Pedicle System dated 2025-02-06
364530_A213328MED KONG® VBR implants dated 2024-12-16

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

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2024-02-13	1000164642	Addition of Product "VADER® Pedicle System Instruments", Product extension VADER® Pedicle System, Addition of Product "KONG® VBR implants"
02	2025-03-13	1000217087	Addition further Basic-UDI-DI for the products "VADER® Pedicle System Instruments" and "VADER® Pedicle System"
03	2025-08-07	1000248990	Addition of Products "KONG®-C VBR and KONGR®-TL VBR Instruments", "icotec Anterior Cervical Plate Instruments", "Cervical Cages Instruments" and "Lumbar Cages Instruments"