EU Quality Management Certificate

This is to certify that the company

icotec ag

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	1000164642
Effective date	2024-02-13
Expiry date	2029-02-12
Frankfurt am Main,	2024-02-13

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)

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 this certificate can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: CH-MF-000026833
Certificate ID: 1000164642

Authorised Representative of the company:

EU Representative

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 - 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
Intended purpose:	The icotec Pedicle Systems are intended to provide immobilization and stabilization of spinal segments.

Examinations and tests performed:
364530_A212274MED dated 2023-04-21

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	n/a	n/a	n/a