



EU Technical Documentation Assessment Certificate

This is to certify that the company



icotec ag

Industriestrasse 12
9450 Altstätten
Switzerland

SRN: CH-MF-000026833

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity
Assessment Procedures according to Article 52. The Technical Documentation is subject to
regular surveillance. Limitations to this certificate are listed in the Annex.

Devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2
listed in the Annex may bear the CE marking with the identification number of the Notified Body
(0297).

For placing devices listed in the Annex on the market, an additional certificate according to Annex
IX, Chapter I and III is required.

Certificate registration no.	364530 MDR2017P
Certificate ID	1000218399
Effective date	2025-03-03
Expiry date	2029-02-12
Frankfurt am Main,	2025-03-03



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 Technical Documentation Assessment Certificate
SRN of Manufacturer: CH-MF-000026833
Certificate ID: 1000218399

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
Models:	Pedicle Screw Carbon/PEEK, Pedicle Screw Ti, Pedicle Rod Carbon/PEEK, Pedicle Rod Ti, Nut Screw Ti, Cross Link Ti
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.

Examinations and tests performed:

364530_A211180MED dated 2023-12-29

364530_A216062MED VADER® Pedicle System dated 2025-02-06

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	1000164646	Product extension VADER® Pedicle System