CERTIFICATE

This is to certify that the company

icotec ag

Industriestrasse 12
9450 Altstätten
Switzerland

with the organizational units/sites as listed in the annex
has implemented and maintains a **Quality Management System**.

Scope of certification:
Design and development, manufacturing and distribution of Spinal cages, sterile and non-sterile bone-screw internal spinal fixation systems and non-bioabsorbable orthopaedic fixation plates and design and development and distribution of reusable surgical instruments.
-AUS (a), BRA, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	364530 MDSAP16
Certificate unique ID	170770584
Effective date	2020-08-26
Expiry date	2023-08-25
Frankfurt am Main	2020-08-26

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

Annex to certificate
Certificate registration No.: 364530 MDSAP16
Certificate unique ID: 170770584
Effective date: 2020-08-26

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Industriestrasse 12
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Audited site

icotec ag

Industriestrasse 12
9450 Altstätten
Switzerland

DUNS No., site scope and country-specific requirements

Design and development, manufacturing and distribution of Spinal cages, sterile and non-sterile bone-screw internal spinal fixation systems and non-bioabsorbable orthopaedic fixation plates and design and development and distribution of reusable surgical instruments.
-AUS (a), BRA, USA (a,b,c,d)
DUNS No. 480789465

Annex to certificate
Certificate registration No.: 364530 MDSAP16
Certificate unique ID: 170770584
Effective date: 2020-08-26

icotec ag

Industriestrasse 12
9450 Altstätten
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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821