CERTIFICATE

This is to certify that the company

mediCAD Hectec GmbH

Opalstraße 54
84032 Landshut - Altdorf
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
The design and development, manufacturing, distribution and servicing of planning and visualization software for orthopedists and surgeons
-AUS (a), BRA, CAN, JPN, 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.	512917 MDSAP16
Certificate unique ID	1000177086
Effective date	2024-08-06
Expiry date	2027-08-05
Frankfurt am Main	2024-07-04

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

Annex to certificate
Certificate registration No.: 512917 MDSAP16
Certificate unique ID: 1000177086
Effective date: 2024-08-06

mediCAD Hectec GmbH

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Audited site	**REPs FEI No.: site scope and country-specific requirements**
512917 **mediCAD Hectec GmbH** Opalstraße 54 84032 Landshut - Altdorf Germany	The design and development, manufacturing, distribution and servicing of planning and visualization software for orthopedists and surgeons **-AUS (a), BRA, CAN, JPN, USA (a,b,c,d)** **FEI No.: F001511**

Annex to certificate
Certificate registration No.: 512917 MDSAP16
Certificate unique ID: 1000177086
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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. 665/2022 RDC ANVISA n. 551/2021 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