



# CERTIFICATE



This is to certify that the company

## mediCAD Hectec GmbH

Opalstraße 54  
84032 Altdorf  
Germany

with the organizational units/sites as listed in the annex

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

Scope of certificate and applicable country-specific requirements:

The design and development, manufacturing, distribution and servicing of medical software used for presurgical, orthopaedic planning applicable in the clinical area of surgery and accident surgery.

- AUS (a), BRA, CND, 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 (MDSAP Audit Model Edition 2)

including country-specific requirements as shown in the scope  
(full references are listed in the annex)

Certificate registration no.	512917 MDSAP16
Certificate unique ID	170708520
Effective date	2018-07-30
Expiry date	2021-07-29
Frankfurt am Main	2018-07-30



### DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director

Szymon Kurdyn  
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [medical.devices@dqs-med.de](mailto:medical.devices@dqs-med.de)

DQS Medizinprodukte GmbH is authorised under the Medical Devices Single Audit Program.  
Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



**Annex to certificate**  
**Certificate registration No.: 512917 MDSAP16**  
**Certificate unique ID: 170708520**  
**Effective date: 2018-07-30**

## **mediCAD Hectec GmbH**

Opalstraße 54  
84032 Altdorf  
Germany

<b>Audited site</b>	<b>DUNS No., site scope and country-specific requirements</b>
<b>mediCAD Hectec GmbH</b> Opalstraße 54 84032 Altdorf Germany	The design and development, manufacturing, distribution and servicing of medical software used for presurgical, orthopaedic planning applicable in the clinical area of surgery and accident surgery. <b>- AUS (a), BRA, CND, USA (a, b, c, d)</b> <b>DUNS. No. 328565361</b>

### **Full references of country-specific requirements of MDSAP participating Regulatory Authorities**

<b>Abbreviation</b>	<b>Jurisdiction</b>	<b>Reference</b>
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