Safety and Performance Information for

mediCAD®

Revision 1.0

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mediCAD® has been validated for its intended purpose. If you experience any software malfunctions or unexpected behavior, or if you have any suggestions for additional functions that could support clinical use, please contact us at:
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Table of contents

1. Product identification 4
2. Applicable software components 4
3. Intended purpose 4
4. Intended users 4
5. Intended patient population 5
6. Clinical benefits and performance 5
7. Key performance characteristics 5
8. Contraindications 5
9. Warnings and precautions 6
10. Residual risks 7
11. Device classification 7
12. EU Declaration of Conformity 8
13. Vigilance and incident reporting 8
14. Electronic Instructions for Use 8

1. Product identification

Product:	mediCAD®
Manufacturer:	mediCAD Hectec GmbH
Address:	Opalstrasse 54, 84032 Altdorf, Germany
Basic UDI-DI:	426048972MCADBW
Classification:	Class IIa medical device according to Regulation (EU) 2017/745
CE Marking:	CE 0483

2. Applicable software components

mediCAD® Desktop
UDI-DI: 04260489720110

mediCAD® Web
UDI-DI: 04260489720202

The commercial packages Core, Plus and Complete differ only in the scope of the licensed modules and are not separate regulatory device variants.

3. Intended purpose

mediCAD® is a package of modules (2D, 3D and web modules) intended for use by trained healthcare professionals. It allows the assessment of bone and joint deformities and the planning of joint-replacing implants and osteotomies based on medical 2D images (X-ray, CT, MRI) and 3D images (CT, MRI, DVT).

4. Intended users

mediCAD® is intended for use by appropriately qualified and trained:

- Orthopedic surgeons
- Trauma surgeons
- Radiologists

Users must have the necessary medical knowledge, complete appropriate product training and read the current electronic Instructions for Use before using mediCAD®.

5. Intended patient population

mediCAD® is intended for patients for whom suitable medical images of the relevant skeletal structures are available and whose treatment is being planned by a qualified healthcare professional.

Typical indications include:

- Surgical or orthopedic conditions requiring surgical intervention
- Joint degeneration associated with restricted mobility and/or resulting pain
- Congenital or acquired deformities requiring surgical intervention

6. Clinical benefits and performance

mediCAD® supports healthcare professionals through:

- Assessment of bone and joint deformities
- Digital distance and angle measurements
- Planning of joint-replacing implants
- Documented and traceable preoperative planning

mediCAD® supports the clinical planning process. It does not replace professional clinical judgement or intraoperative verification.

7. Key performance characteristics

Distance measurement accuracy:	± 0.6 mm
Angle measurement accuracy:	± 0.2°
Scaling accuracy:	± 0.5%

Depending on image acquisition, calibration, scaling and processing conditions, deviations of up to 2 mm may occur. All measurements and planning results must be clinically reviewed and verified by the responsible healthcare professional.

8. Contraindications

No contraindications have been identified for the intended use of mediCAD®.
mediCAD® is not intended to provide a diagnosis.

9. Warnings and precautions

mediCAD® may only be used by appropriately qualified and trained personnel.

Patient assignment, image quality, image orientation, DICOM information and image scaling must be verified before measurements or planning are performed. Applicable image-acquisition and scan guidelines must be followed.

When a reference object is used, its dimensions and anatomical position must be verified. Incorrect positioning or scaling values may lead to significant planning errors. The scaling sphere provided by mediCAD has a diameter of 25 mm with a tolerance of ± 0.1 mm.

Automatically generated measurements, implants, screws, rods and other planning elements are suggestions only and must be clinically reviewed and corrected where necessary.

Final implant selection, positioning and treatment decisions remain the responsibility of the healthcare professional and must be verified intraoperatively where applicable.

Image processing, image merging and incomplete DICOM information may result in measurement or dimensional deviations.

Software, database or network interruptions may affect the availability of images, implant data or planning results. Proper system operation and the relevant planning information must be verified before clinical use.

10. Residual risks

The residual risks associated with mediCAD® are indirect and may result from:

- Unsuitable or incorrectly assigned medical images
- Incomplete or incorrect DICOM information
- Scaling or measurement deviations
- Incorrect user input
- Unverified automatic planning suggestions
- Incorrect implant selection or positioning
- Image-processing tolerances
- Software, database or network interruptions
- Use by insufficiently qualified or trained personnel

If not detected during clinical review, such errors may lead to incorrect preoperative planning and potential patient harm.

These risks are reduced through user qualification and training, software warnings, verification of images, scaling and planning results, and final clinical review by the responsible healthcare professional.

The identified residual risks have been assessed as acceptable when mediCAD® is used for its intended purpose and in accordance with the current electronic Instructions for Use.

11. Device classification

mediCAD® is classified as a Class IIa medical device in accordance with Regulation (EU) 2017/745, Annex VIII, Rule 11.
The conformity assessment was performed with the involvement of Notified Body No. 0483.
CE 0483

12. EU Declaration of Conformity

The current EU Declaration of Conformity for mediCAD® is available on the mediCAD® website.

13. Vigilance and incident reporting

All incidents, suspected malfunctions or safety-related events associated with mediCAD® should be reported without undue delay to:

mediCAD Hectec GmbH
Quality Management / Regulatory Affairs
Opalstrasse 54
84032 Altdorf
Germany
Email: support@medicad.eu
Telephone: +49 871 330 203-0

Any serious incident related to mediCAD® should also be reported to the competent authority of the Member State in which the user and/or patient is established.

14. Electronic Instructions for Use

The current electronic Instructions for Use are available:

- Within mediCAD®

Users must ensure that they consult the electronic Instructions for Use applicable to the relevant software version and language. A paper copy of the Instructions for Use may be requested from mediCAD Hectec GmbH at no additional cost.

mediCAD
The Digital Mind For Orthopedics