

EU - DECLARATION OF CONFORMITY

for the
mediCAD®

Manufacturer	mediCAD Hectec GmbH
SRN (Single Registration Number):	DE-MF-000006987
Address	D-84032 Altdorf (Landshut)Opalstraße 54
Device name	mediCAD®
Basic UDI-DI	426048972MCADBW
Version number	Desktop version 8.0 Web version 2.7
class	According to Annex VIII of MDR 2017/745, the product is classified as Class IIa according to Rule 11
Conformity assessment procedure;	EU Regulation 2017/745 Annex IX

Intended use

mediCAD® is a package of software modules (2D, 3D and web modules) intended for use by trained medical professionals. Based on medical 2D and 3D images, on which digital and precise measurements can be carried out with mediCAD®, the software allows an assessment of bone and joint deformities and the subsequent planning of joint-replacing and joint-preserving orthopaedic and trauma surgery, including the implants required for this. mediCAD® is a medical software. Consequently, the product does not come into contact with the patient. It is not implantable, invasive or comes into contact with human skin.

Valid from; *effective date*: **12.05.2026**

We, mediCAD Hectec GmbH, declare that the issue of this declaration of conformity is our sole responsibility.

We hereby declare that mediCAD® complies with all applicable requirements of EU Regulation 2017/745 on medical devices (MDR).

Our quality management system is certified in accordance with DIN EN ISO 13485 and is subject to monitoring by the accredited certification body.

mdc
medical device certification GmbH
Kriegerstrasse 6
D-70191 Stuttgart
Germany



Landshut, 12.05.2026

A handwritten signature in black ink, appearing to be 'Lars Thursar', written over a horizontal line.

Lars Thursar
CEO