MedCom Gesellschaft für medizinische Bildverarbeitung mbH
Dolivostraße 11 · 64293 Darmstadt · Germany
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BiopSee®
3.3 build 3

Declaration of Conformity

The medical device software for diagnosis (Class IIa) **BiopSee® 3.3 Build 3** meets the provision of the Medical Device Directive 93/42/EEC, Annex I, amended by Directive 2007/47/EC, and its transposition into national legislation of the member states. The CE marking of conformity applied to this device encompasses all other relevant directives.

Basic-UDI-DI: 0426030811BiopSeeVV

The device is manufactured by MedCom Gesellschaft für medizinische Bildverarbeitung mbH, who is exclusively responsible for this declaration of conformity.

MedCom has established and maintains a quality management system according to the requirements of Annex II, excluding section 4, of the Medical Devices Directive under the supervision of the notified body DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt a. M. (0297).

This declaration is bound to the validity of certificate 276701MR2.

Darmstadt, 21 MAY 2021

MEDCOM
MedCom GmbH

Georgios Sakas, CEO