



EC Declaration of Conformity

in accordance with EC Directive 93/42/EEC on Medical Devices

Manufacturer Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52, 07745 Jena, Germany

We Carl Zeiss Meditec AG herewith declare with sole responsibility that the following Medical Device meets the Requirements of the European Directive 93/42/EEC. The Device is provided with CE Marking.

Product identification:	<i>Fundus Viewing System</i>
Medical Device Trade Name:	<i>RESIGHT 500 RESIGHT 700 RESIGHT metal tray</i>
Models/Reference:	<i>302721-9020-000 302721-9030-000 302721-9250-000</i>
Accessories:	<i>Asepsis Caps</i>
Medical Device Class:	
MDD 93/42/EEC	<i>Class I</i>
Conformity Assessment Procedure :	<i>Annex VII of MDD 93/42/EEC</i>
Scope of Application:	This Declaration of Conformity is valid for all products manufactured until 2020-06-08.
UMDNS code:	<i>12-818</i>
GMDN code:	<i>47946</i>

We established and maintain a Quality Management System in accordance to EN ISO 13485:2012+AC:2012 which has been audited by DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt.

Any Modification to the product not authorized by Carl Zeiss Meditec AG will invalidate this Declaration.

i. V. Alexandre Mariet
Vice President Competence Center
Surgical Devices & Systems

i.V. Dr. Christian Muenster
Director Regulatory Affairs