



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: *Fundus Viewing System*

Medical Device Trade Name: *RESIGHT 500
RESIGHT 700
RESIGHT metal tray*

Models/Reference: *302721-9020-000
302721-9030-000
302721-9250-000*

Accessories: *Asepsis Caps*

Medical Device Class:
MDD 93/42/EEC *Class I*

Conformity Assessment Procedure : *Annex VII of MDD 93/42/EEC*

Scope of Application: This Declaration of Conformity is valid for following serial numbers 2020-06-08.

UMDNS code: *12-818*

GMDN code: *47946*

We established and maintain a Quality Management System in accordance to EN ISO 13485: 2016 + AC: 2016 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.

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