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:	***Surgical Microscope***
Medical Device Trade Name:	***TIVATO 700***
Models/Reference:	***REF: 6643***
Accessories:	***INFRARED 800, SMARTDRAPE, Monitor, ConnectApp, 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 all products manufactured until 2020-06-11.
UMDNS code:	***12-539***
GMDN code:	***35191***

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

Oberkochen, 2018-11-21

MO-MANU-0038

EC Declaration of Conformity

in accordance with EC Directive 2011/65/EU on RoHS

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

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product identification:	***Surgical Microscope***
Medical Device Trade Name:	***TIVATO 700***
Models/Reference:	***REF: 6643***
Conformity Assessment Procedure :	***According to Directive 2011/65/EU***
Scope of Application:	This Declaration of Conformity is valid for all products manufactured until 2020-06-11.
Standards Applied:	EN 50581:2012

The object of the declaration of conformity described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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

i.V. Dr. Christian Muenster
Director Regulatory Affairs

Oberkochen, 2018-11-21

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