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 under our sole responsibility that the following Medical Device meets the applicable Requirements of the European Directive 93/42/EEC. The Device is provided with CE Marking.

Product identification:	Surgical Microscope
Medical Device Trade Name:	**S8 / OPMI Lumera T**
Reference Number:	000000-1176-968
Accessories:	Foot Control Panel, MediLive Trio Eye, TRIO 600, MEDIALINK 100, RESIGHT 500, RESIGHT 700, Monitor, Asepsis Caps
Medical Device Class:	
MDD 93/42/EEC	I
Conformity Assessment Procedure :	According to Annex VII of MDD 93/42/EEC
Scope of Application:	This Declaration of Conformity is valid for all products manufactured until 2017-08-20
UMDNS classification:	12-539
GMDN Code:	32817
Standards Applied:	EN ISO 14971:2012 EN 60601-1:2006/AC:2010 EN 60601-1-2:2007/AC:2010 EN 60601-1-6:2010 EN 62366:2008 EN ISO 13485:2012+AC:2012

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.

ppa Dirk Brunner
Senior Vice President Microsurgery Division

i. V. Sarah Haake-Schaefer
Director of Regulatory and Clinical Affairs

Oberkochen, 2014-08-21

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