Beglaubigte Abschrift

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:	***KINEVO 900***
Models/Reference:	***6640***
Accessories:	***BLUE 400, YELLOW 560, INFRARED 800 with FLOW 800 option, QEVO, QEVO ECU, SMARTDRAPE, FCP WL***
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 products manufactured until 2022-07-24.
UMDNS code:	***12-539***
GMDN code:	***41895***

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.

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

i.V. Peter Schrutka-Rechtenstamm
Senior Director Regulatory and Clinical Affairs

Oberkochen, 2019-07-24

MO-TOKY-0064

Notar Kurz
Aalen

Die Übereinstimmung der Ablichtung
mit der mir vorliegenden Urschrift
wird

b e g l a u b i g t .

Aalen, den 08.11.2019

Kurz
Notar

WINFRIED KURZ
NOTAR IN AALEN