EU Declaration of Conformity

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

Manufacturer: *Carl Zeiss Meditec, Inc., 5160 Hacienda Drive, Dublin 94568, CA, USA*

We, Carl Zeiss Meditec, Inc., herewith declare under our sole responsibility that the following Medical Device meets the Requirements of the European Directive 93/42/EEC.

Product identification:	*UMDNS: spectral-domain optical coherence tomography systems* *GMDN: spectral-domain optical coherence tomography systems*
Medical Device Name / Trade Name:	*CIRRUS HD-OCT*
Models/Reference:	*6000*
Accessories:	*Instrument Table*
Medical Device Class	*Class IIa*
Conformity Assessment Procedure	*Annex II of MDD 93/42/EEC excluding Section 4*
Scope of Application:	*This Declaration of Conformity is valid for all products manufactured until 2024-05-22*
UMDNS classification:	*18-191*
GMDN Code:	*58850*
Notified Body:	*DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt – notified under 0297.*
Certificate Registration Number:	*250712 MR2*
EU Representative:	*Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52, 07745 Jena, Germany*

Any modification to the product not authorized by Carl Zeiss Meditec, Inc. will invalidate this declaration.

Viet Nguyen
Director, Quality Management
& Quality Management Representative

Issuing Site: Carl Zeiss Meditec, Inc., Dublin, CA 94568, USA

Signed by / Podpisano przez:
Marcin Tomasz Trebicki
CARL ZEISS Sp. z o.o.
Date / Data: 2021-05-25 14:37

Signed by / Podpisano przez:
Michał Reimus
CARL ZEISS Sp. z o.o.
Date / Data: 2021-05-25 14:51