EU-Examination Certificate

This is to certify that the company

Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52
07745 Jena
Germany

has implemented a complete Quality Management System for each phase from Design to Final Testing of the products.

Through an audit, documented in a report, carried out by DQS Medizinprodukte GmbH, the proof was provided that this quality management system meets the requirements according to

Annex IX of the Regulation (EU) 2017/745

CONFORMITY ASSESSMENT PROCEDURE ON THE BASIS OF A QUALITY MANAGEMENT SYSTEM AND AN ASSESSMENT OF THE TECHNICAL DOCUMENTATION

regarding the medical devices listed in the Annex:
The manufacturer shall be subject to surveillance in accordance with Annex IX, Chapter 1, Section 3.
The CE marking with the identification number of the Notified Body (0297) may be affixed on the devised listed on the certificate.

Certificate registration no.	DE-MF-000007732
Certificate ID	170778938
Previous certificate-ID	n/a
Effective date	2021-12-02
Expiry date	2026-12-01
Frankfurt am Main,	2021-12-02

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.

420.92 Version 1.0

Annex to EU-Examination Certificate
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Product name	Model	Type	Intended Use	Risk class	Basic UDI-DI
CT SPHERIS 204 CT SPHERIS 209M CT ASPHINA 404 CT ASPHINA 409M CT ASPHINA 409MP CT ASPHINA 509M CT ASPHINA 509MP	n/a	n/a	This ZEISS intraocular lens is intended for implantation in the capsular bag to replace the human crystalline lens.	IIb	4049336_P01_M01_R2B_VF
AT TORBI 709M AT TORBI 709MP AT TORBI 719M AT TORBI 719MP	n/a	n/a	This ZEISS intraocular lens is intended for implantation in the capsular bag to replace the human crystalline lens.	IIb	4049336_P02_M01_R2B_WC
AT LARA toric 929M AT LARA toric 929MP AT LISA toric 909M AT LISA toric 909MP AT LISA tri toric 939M AT LISA tri toric 939MP AT LISA tri toric 949M AT LISA tri toric 949MP	n/a	n/a	This ZEISS intraocular lens is intended for implantation in the capsular bag to replace the human crystalline lens.	IIb	4049336_P03_M01_R2B_X9
AT LISA 809M AT LISA 809MP AT LARA 829MP AT LISA tri 839MP	n/a	n/a	This ZEISS intraocular lens is intended for implantation in the capsular bag to replace the human crystalline lens.	IIb	4049336_P04_M01_R2B_Y6

Examinations and tests performed (e.g. Reference to relevant CS, harmonised standards, test reports and audit report):
21_Zeiss_MDR_TD_Review_Hydrophilic_IOL dated 2021-06-18

Reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered:
n/a

Conditions or limitations regarding the validity of the certificate:
n/a