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 with the number of the Notified Body.

Product identification:	***Surgical Drapes***
Medical Device Trade Name:	***Surgical Drapes, sterile***
Models/Reference:	***OPMI Drapes sterile*** ***306025-0000-000*** ***306026-0000-000*** ***306070-0000-000*** ***306071-0000-000*** ***306073-0000-000*** ***306075-0000-000*** ***306079-0000-000*** ***326005-0000-000*** ***326009-0000-000*** ***326013-0000-000*** ***326018-0000-000*** ***326082-0000-000*** ***DRAPES sterile*** ***326088-0000-000*** ***Drapes*** ***326035-0000-000*** ***326038-0000-000*** ***306084-0000-000*** ***SMARTDRAPE*** ***306028-0000-000*** ***VisionGuard Replacement Lenses*** ***306001-0000-000*** ***INTRABEAM Drape*** ***326090-0000-000***
Medical Device Class: MDD 93/42/EEC	***Class Is***
Conformity Assessment Procedure :	***Annex II of MDD 93/42/EEC***
Scope of Application:	This Declaration of Conformity is valid for all products manufactured until 2024-05-26.
UMDNS code:	***15-775***
GMDN code:	***12535***

Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt - notified under 0297.

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. Hans-Joachim Miesner
Director Regulatory Affairs
and Clinical Affairs

Oberkochen, 2021-11-23

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