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***

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

Models/Reference:

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

Digitally signed by Gherman Irina
Date: 2025.06.23 08:20:21 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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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