Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- *the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and*
- *the compliance of the devices and us as manufacturer with the conditions for the continued placing on the market and putting into service*

Manufacturer: Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52, 07745 Jena, Germany

Authorised representative: n/a

Single Registration Number: DE-MF-000007732

We, Carl Zeiss Meditec AG, herewith declare under our sole responsibility that the conditions for legal extension of validity as required in Article 120.2 of the MDR are met. The listed device(s) and we as manufacturer are in compliance with conditions listed in Article 120.3c of the MDR for continued placing on the market und putting into service by fulfilling the following:

➢ **Directive Certificate(s)** as listed below

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired before 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed below or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

36 ☒ Expired/expires after 20 March 2023:

Choose one applicable statement:

37 ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph
38 of Annex VII MDR for conformity assessment has/have been made or will be made/submitted
39 by us to a notified body no later than 26 May 2024 for the device(s) listed below or its/their
40 substitute(s) and signed written agreement(s) is/will be in place in accordance with Section
41 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

42 ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024,
43 therefore the transition period will end on 26 May 2024

44 ➢ **Quality Management System (QMS)**

Choose one applicable statement:

45 ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

46 ☒ A QMS in accordance with Article 10(9) MDR is in place.

47 ☐ A notified body has issued a certificate for the MDR-compliant QMS.

48 ➢ **Device(s) as listed in the attached table:**

49 • The device(s) continue to comply with the requirements of European Directive 93/42/EEC.
50 • There are no significant changes in the design and intended purpose.
51 • The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or
52 to other aspects of the protection of public health.

53 **Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt**
54 **– notified under 0297**

Electronically signed by: Christian Muenster
Reason: I am approving this document
Date: Apr 24, 2024 09:14 GMT+2

Electronically signed by: Michael Schmidt
Reason: I am approving this document
Date: Apr 12, 2024 08:26 GMT+2

55 i.V. Christian Muenster
56 Head of Global Regulatory Affairs & Clinical Affairs

i.V. Michael Schmidt
Head of Global Quality Management MED

57 **Devices:**

58 The above Manufacturer's Declaration is valid for the following devices:

Certificate Unique ID	Original Certificate Expiry Date	Device Family / Devices	Class	Product Identification	Medical Device Trade Name	Substitute MDR Device (if applicable)	End Date of Extended Validity
170774133	**2024-05-26**	Medical Equipment Drape, single-use sterile	Is	Surgical Drapes	Surgical Drapes, sterile (OPMI Drapes sterile, DRAPES sterile, Drapes, SMARTDRAPE, VisionGuard Replacement Lenses, INTRABEAM Drape)	N/A	**2028-12-31**
170774133	**2024-05-26**	Surgical Microscope incl. Fluorescence Option	IIa	Surgical Microscope	OPMI PENTERO 800 with options BLUE 400, YELLOW 560, INFRARED 800, FLOW 800	INFRARED 800 with FLOW 800 Option	**2028-12-31**
170774133	**2024-05-26**	Radiosurgery Treatment Systems	IIb	Radiotherapy System	INTRABEAM 600	INTRABEAM 700	**2028-12-31**
170774133	**2024-05-26**	Radiosurgery Treatment Systems	IIa	Accessory for Radiosurgery Treatment System	INTRABEAM Flat Applicator Set	N/A	**2028-12-31**
170774133	**2024-05-26**	Radiosurgery Treatment Systems	IIa	Accessory for Radiosurgery Treatment System	INTRABEAM Surface Applicator Set	N/A	**2028-12-31**
170774133	**2024-05-26**	Radiosurgery Treatment Systems	Im	Accessory for Radiosurgery Treatment System	INTRABEAM Water Phantom	N/A	**2028-12-31**
170774133	**2024-05-26**	Radiosurgery Treatment Systems	III	INTRABEAM Spherical Applicator (accessory to Radiosurgery Treatment Systems)	INTRABEAM Spherical Applicator	INTRABEAM SMART Spherical Applicator	**2027-12-31**
170768644*	**2024-05-26**						
170774133	**2024-05-26**	Radiosurgery Treatment Systems	III	INTRABEAM Needle Applicator (accessory to Radiosurgery Treatment Systems)	INTRABEAM Needle Applicator	N/A	**2027-12-31**
170766276*	**2024-05-26**						

Certificate Unique ID	Original Certificate Expiry Date	Device Family / Devices	Class	Product Identification	Medical Device Trade Name	Substitute MDR Device (if applicable)	End Date of Extended Validity
170774133	**2024-05-26**	Sterile Sheath for CONVIVO	III	Sterile Sheath for Confocal Endomicroscope	Sterile Sheath for CONVIVO	N/A	**2027-12-31**
170710972*	**2023-04-13**						
170774133	**2024-05-26**	Patient health record information system application software	IIa	Image and Report Management System	FORUM	N/A	**2028-12-31**
170774133	**2024-05-26**	Patient health record information system application software	IIa	Image and Report Management System	Glaucoma Workplace	N/A	**2028-12-31**
170774133	**2024-05-26**	Patient health record information system application software	IIa	Image and Report Management System	Retina Workplace	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	IRR & ASP Handpieces	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	PHACO & SLEEVE SETS	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	ADVANCED IRRIGATION TUBINGS	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	Is	Accessory to Phacoemulsificationssystem	QUATERA 700 COVERS	N/A	**2028-12-31**

Certificate Unique ID	Original Certificate Expiry Date	Device Family / Devices	Class	Product Identification	Medical Device Trade Name	Substitute MDR Device (if applicable)	End Date of Extended Validity
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Lens Fragmentation Device	miLOOP	N/A	**2028-12-31**
170774133	**2024-05-26**	Applanation Tonometer	Im	Applanation Tonometer	AT 020	N/A	**2028-12-31**
170774133	**2024-05-26**	Applanation Tonometer	Im	Applanation Tonometer	AT 030	N/A	**2028-12-31**
170774133	**2024-05-26**	Ophthalmic Examination Unit	IIa	Autorefractor / Keratometer	VISUREF 150	N/A	**2028-12-31**
170774133	**2024-05-26**	Ophthalmic Examination Unit	IIa	Non-contact Tonometer	VISUPLAN 500	N/A	**2028-12-31**
170774133	**2024-05-26**	Ophthalmic Lasers and accessories	IIb	Ophthalmic Therapy Laser	VisuMax including Treatment Pack (sterile accessory for VisuMax)	N/A	**2028-12-31**
170774133	**2024-05-26**	Ophthalmic Lasers and accessories	IIa	Accessory for Ophthalmic Therapy Laser	Treatment Pack (sterile accessory for fs-lasers of ZEISS)	N/A	**2028-12-31**
170774133	**2024-05-26**	Ophthalmic Lasers and accessories	IIb	Excimer Laser	MEL 80 with Option CRS-Master and accessories	MEL 90	**2028-12-31**
170774133	**2024-05-26**	Ophthalmic Examination Unit	IIa	Biometry Device	IOLMaster 500	N/A	**2028-12-31**
170774133	**2024-05-26**	Ophthalmic Lasers and accessories	IIb	Ophthalmic Therapy Laser	VISULAS green	VISULAS green	**2028-12-31**

Certificate Unique ID	Original Certificate Expiry Date	Device Family / Devices	Class	Product Identification	Medical Device Trade Name	Substitute MDR Device (if applicable)	End Date of Extended Validity
170774133	**2024-05-26**	Ophthalmic Lasers and accessories	IIb	Ophthalmic Therapy Laser	VISULAS YAG III	VISULAS yag	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIb	Accessory to Phacoemulsificationssystem	ULITE PHACO HANDPIECE	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	PHACO TIPS REUSABLE	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	SILICONE SLEEVES	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	I/A HANDPIECE,COAXIAL,REUSABLE	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	I/A CANNULA, METAL SLEEVE	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	IRRIGATION HANDPIECE, BIMANUAL	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	ASPIRATION HANDPIECE, BIMANUAL	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	I/A CANNULA, SILICONE SLEEVE	N/A	**2028-12-31**

Certificate Unique ID	Original Certificate Expiry Date	Device Family / Devices	Class	Product Identification	Medical Device Trade Name	Substitute MDR Device (if applicable)	End Date of Extended Validity
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	I/A TUBING SET, REUSABLE	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	I/A TUBING CASSETTE QUICKSET	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	IRRIGATION ADMINISTRATION SET	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIb	Accessory to Phacoemulsificationssystem	DIATHERMY PROBES	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIb	Accessory to Phacoemulsificationssystem	20G A-VIT PROBE WITH SLEEVE	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	Is	Accessory to Phacoemulsificationssystem	SCREEN COVER & MAYO DRAPE	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	Is	Accessory to Phacoemulsificationssystem	SCREEN DRAPE VISALIS 500	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	Is	Accessory to Phacoemulsificationssystem	TRAY COVER VISALIS 500	N/A	**2028-12-31**

Certificate Unique ID	Original Certificate Expiry Date	Device Family / Devices	Class	Product Identification	Medical Device Trade Name	Substitute MDR Device (if applicable)	End Date of Extended Validity
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIb	Accessory to Phacoemulsificationssystem	POSTERIOR VITRECTOMY PROBES	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	20G SCLERAL INFUSION CANNULA	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	VISCOUS FLUID REMOVAL KIT	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	AIR INJECTION TUBE WITH FILTER	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	Is	Accessory to Phacoemulsificationssystem	SILICONE OIL INJECTION TUBE	N/A	**2028-12-31**
170774133	**2024-05-26**	Phacoemulsification Systems and accessories	IIa	Accessory to Phacoemulsificationssystem	ENDO-ILLUMINATION PROBES	N/A	**2028-12-31**

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* Certificate refers to EC Design Examination according 93/42/EEC Annex II Section 4 relevant for Class III medical devices