

## Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52  
07745 Jena  
Germany

Date: 08.03.2024

### Notified Body Confirmation Letter

Reference: 1000169753

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of 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

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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Goeschwitzer Strasse 51 - 52  
07745 Jena  
Germany

SRN: DE-MF-000007732

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices. The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Name

(Alexander Spizyn)

Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
AT TORBI 709M 4049336_P02_M01_R2B_WC	Class IIb implantable	N/A	170774133, NB 0297
AT TORBI 709MP 4049336_P02_M01_R2B_WC	Class IIb implantable	N/A	170774133, NB 0297
AT LISA tri toric 939M 4049336_P03_M01_R2B_X9	Class IIb implantable	N/A	170774133, NB 0297
AT LISA tri toric 939MP 4049336_P03_M01_R2B_X9	Class IIb implantable	N/A	170774133, NB 0297
AT LISA toric 909M 4049336_P03_M01_R2B_X9	Class IIb implantable	N/A	170774133, NB 0297
AT LISA toric 909MP 4049336_P03_M01_R2B_X9	Class IIb implantable	N/A	170774133, NB 0297
AT LISA 809MP 4049336_P04_M01_R2B_Y6	Class IIb implantable	N/A	170774133, NB 0297
AT ELANA 841P 4049336_P04_M03_R03_XC	Class III	N/A	170774133, NB 0297
CT LUCIA 201P 4049336_P01_M03_R03_UM	Class III	N/A	170774133, NB 0297
CT LUCIA 601P 4049336_P01_M03_R03_UM	Class III	N/A	170774133, NB 0297
CT LUCIA 601PY 4049336_P01_M03_R03_UM	Class III	N/A	170774133, NB 0297
CT LUCIA 611P 4049336_P01_M03_R03_UM	Class III	N/A	170774133, NB 0297
CT LUCIA 611PY 4049336_P01_M03_R03_UM	Class III	N/A	170774133, NB 0297
CT LUCIA 211P 4049336_P01_M03_R03_UM	Class III	N/A	170774133, NB 0297
CT LUCIA 211PY 4049336_P01_M03_R03_UM	Class III	N/A	170774133, NB 0297
CT LUCIA 202 4049336_P01_M04_R2B_WN	Class IIb implantable	N/A	170774133, NB 0297
CT LUCIA 602 4049336_P01_M04_R2B_WN	Class IIb implantable	N/A	170774133, NB 0297
RT SIL-OL 1000 4049336_P05_M06_R2B_37	Class IIb implantable	N/A	170774133, NB 0297
RT SIL-OL 5000 4049336_P05_M06_R2B_37	Class IIb implantable	N/A	170774133, NB 0297
Z-CELCOAT 4049336_P06_M07_R2B_4H	Class IIb	N/A	170774133, NB 0297

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
RT DECALIN 4049336_P05_M05_R2B_2S	Class IIa	N/A	170774133, NB 0297
RT OCTA 4049336_P05_M05_R2B_2S	Class IIa	N/A	170774133, NB 0297
PURI CLEAR 4049336_P07_M09_R2A_65	Class IIa	N/A	170774133, NB 0297
BLUEMIXS 180 4049336_P08_M11_R2A_4B	Class IIa	N/A	170774133, NB 0297
AT.Shooter A1-2000 4049336_P08_M12_R1R_66	Class Ir	N/A	N/A - Device did not require a Notified Body certificate under Directives
Surgical Drapes, sterile 4049539_1_0118_RK	Class I device placed on the market in sterile condition	N/A	170774133, NB 0297
INFRARED 800 with FLOW 800 Option 4049539_1_0236_RW	Class IIa	OPMI PENTERO 800 with options BLUE 400, YELLOW 560, INFRARED 800, FLOW 800	170774133, NB 0297
IRR & ASP Handpieces 4049539_1_0019_RF	Class IIa	N/A	170774133, NB 0297
PHACO & SLEEVE SETS 4049539_1_0246_S3	Class IIa	N/A	170774133, NB 0297
ADVANCED IRRIGATION TUBINGS 4049539_1_0192_S9	Class IIa	N/A	170774133, NB 0297
QUATERA 700 COVERS 4049539_1_0470_SE	Class I device placed on the market in sterile condition	N/A	170774133, NB 0297
INTRABEAM 700 4049539_0_6408_TL	Class IIb excluding Class IIb implantable non-WET	INTRABEAM 600	170774133, NB 0297
INTRABEAM Flat Applicator Set 4049539_1_0144_RN	Class IIa	N/A	170774133, NB 0297
INTRABEAM Surface Applicator Set 4049539_1_0144_RN	Class IIa	N/A	170774133, NB 0297
INTRABEAM Water Phantom 4049539_0_0178_SH	Class I devices with a measuring function	N/A	170774133, NB 0297

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
INTRABEAM SMART Spherical Applicator 4049539_1_0156_RZ	Class III	INTRABEAM Spherical Applicator	170774133, 170768644, NB 0297
INTRABEAM Needle Applicator 4049539_0_0137_RS	Class III	N/A	170774133, 170766276, NB 0297
Sterile Sheath for CONVIVO 4049539_1_0342_RW	Class III	N/A	170774133, 170710972, NB 0297
FORUM 4049471_00000007_6E	Class IIa	N/A	170774133, NB 0297
Glaucoma Workplace 4049471_00000002_5X	Class IIa	N/A	170774133, NB 0297
Retina Workplace 4049471_00000001_5U	Class IIa	N/A	170774133, NB 0297
miLOOP 4049539_1_0449_SS	Class IIa	N/A	170774133, NB 0297
Applanation Tonometer AT 020 4049471_AT0001_SK	Class I devices with a measuring function	N/A	170774133, NB 0297
Applanation Tonometer AT 030 4049471_AT0001_SK	Class I devices with a measuring function	N/A	170774133, NB 0297
VISUREF 150 4049471_RDX003_AS	Class IIa	N/A	170774133, NB 0297
VISUPLAN 500 4049471_RDX004_AV	Class IIa	N/A	170774133, NB 0297
VisuMax including Treatment Pack (sterile accessory for VisuMax) 4049471_VM0001_2Y	Class IIb	N/A	170774133, NB 0297
Treatment Pack (sterile accessory for fs-lasers of ZEISS) 4049471_TP0001_35	Class IIa	N/A	170774133, NB 0297
MEL 90 4049471_ML0001_VP	Class IIb	MEL 80 with Option CRS-Master and accessories	170774133, NB 0297

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
IOLMaster 500 4049471_IM0002_U3	Class IIa	N/A	170774133, NB 0297
VISULAS green 4049471_VL0001_2K	Class IIb	VISULAS green	170774133, NB 0297
VISULAS yag 4049471_VL0003_2R	Class IIb	VISULAS YAG III	170774133, NB 0297
ULITE PHACO HANDPIECE 4049539_1_0018_RC	Class IIb excluding Class IIb implantable non-WET	N/A	170774133, NB 0297
PHACO TIPS REUSABLE 4049539_1_0001_QJ	Class IIa	N/A	170774133, NB 0297
SILICONE SLEEVES 4049539_1_0044_RF	Class IIa	N/A	170774133, NB 0297
I/A HANDPIECE, COAXIAL, REUSABLE 4049539_1_0022_QX	Class IIa	N/A	170774133, NB 0297
I/A CANNULA, METAL SLEEVE 4049539_1_0027_RE	Class IIa	N/A	170774133, NB 0297
IRRIGATION HANDPIECE, BIMANUAL 4049539_1_0020_QR	Class IIa	N/A	170774133, NB 0297
ASPIRATION HANDPIECE, BIMANUAL 4049539_1_0021_QU	Class IIa	N/A	170774133, NB 0297
I/A CANNULA, SILICONE SLEEVE 4049539_1_0032_R4	Class IIa	N/A	170774133, NB 0297
I/A TUBING SET, REUSABLE 4049539_1_0043_RC	Class IIa	N/A	170774133, NB 0297
I/A TUBING CASSETTE QUICKSET 4049539_1_0191_S6	Class IIa	N/A	170774133, NB 0297
IRRIGATION ADMINISTRATION SET 4049539_1_0079_SD	Class IIa	N/A	170774133, NB 0297
DIATHERMY PROBES 4049539_1_0050_R8	Class IIb excluding Class IIb implantable non-WET	N/A	170774133, NB 0297

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
20G A-VIT PROBE WITH SLEEVE 4049539_1_0052_RE	Class IIb excluding Class IIb implantable non-WET	N/A	170774133, NB 0297
SCREEN COVER & MAYO DRAPE 4049539_1_0085_S6	Class I devices placed on the market in sterile condition	N/A	170774133, NB 0297
SCREEN DRAPE VISALIS 500 4049539_1_0086_S9	Class I devices placed on the market in sterile condition	N/A	170774133, NB 0297
TRAY COVER VISALIS 500 4049539_1_0088_SF	Class I devices placed on the market in sterile condition	N/A	170774133, NB 0297
POSTERIOR VITRECTOMY PROBES 4049539_1_0089_SJ	Class IIb excluding Class IIb implantable non-WET	N/A	170774133, NB 0297
20G SCLERAL INFUSION CANNULA 4049539_1_0097_SH	Class IIa	N/A	170774133, NB 0297
VISCOUS FLUID REMOVAL KIT 4049539_1_0100_QN	Class IIa	N/A	170774133, NB 0297
AIR INJECTION TUBE WITH FILTER 4049539_1_0101_QR	Class IIa	N/A	170774133, NB 0297
SILICONE OIL INJECTION TUBE 4049539_1_0102_QU	Class I devices placed on the market in sterile condition	N/A	170774133, NB 0297
ENDO-ILLUMINATION PROBES 4049539_1_0103_QX	Class IIa	N/A	170774133, NB 0297

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A (There is no product which this letter covers where DQS is not also responsible for surveillance of the devices under the applicable Directive)	N/A (There is no product which this letter covers where DQS is not also responsible for surveillance of the devices under the applicable Directive)	N/A (There is no product which this letter covers where DQS is not also responsible for surveillance of the devices under the applicable Directive)	N/A (There is no product which this letter covers where DQS is not also responsible for surveillance of the devices under the applicable Directive)

#### Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
08.12.2023	1000147520	Initial issue
08.03.2024	1000169753	<p>Addition of the following devices to Table 1:</p> <p>Surgical Drapes, sterile  INFRARED 800 with FLOW 800 Option  IRR &amp; ASP Handpieces  PHACO &amp; SLEEVE SETS  ADVANCED IRRIGATION TUBINGS  QUATERA 700 COVERS  INTRABEAM 700  INTRABEAM Flat Applicator Set  INTRABEAM Surface Applicator Set  INTRABEAM Water Phantom  INTRABEAM SMART Spherical Applicator  INTRABEAM Needle Applicator  Sterile Sheath for CONVIVO  FORUM  Glaucoma Workplace  Retina Workplace  miLOOP  Applanation Tonometer AT 020  Applanation Tonometer AT 030  VISUREF 150  VISUPLAN 500  VisuMax including Treatment Pack (sterile accessory for VisuMax)  Treatment Pack (sterile accessory for fs-lasers of ZEISS)  MEL 90</p>



Date	NB internal reference traceable to each version of the letter	Action
		IOLMaster 500 VISULAS green VISULAS yag ULITE PHACO HANDPIECE PHACO TIPS REUSABLE SILICONE SLEEVES I/A HANDPIECE, COAXIAL,REUSABLE I/A CANNULA, METAL SLEEVE IRRIGATION HANDPIECE, BIMANUAL ASPIRATION HANDPIECE, BIMANUAL I/A CANNULA, SILICONE SLEEVE I/A TUBING SET, REUSABLE I/A TUBING CASSETTE QUICKSET IRRIGATION ADMINISTRATION SET DIATHERMY PROBES 20G A-VIT PROBE WITH SLEEVE SCREEN COVER & MAYO DRAPE SCREEN DRAPE VISALIS 500 TRAY COVER VISALIS 500 POSTERIOR VITRECTOMY PROBES 20G SCLERAL INFUSION CANNULA VISCOUS FLUID REMOVAL KIT AIR INJECTION TUBE WITH FILTER SILICONE OIL INJECTION TUBE ENDO-ILLUMINATION PROBES