EU Quality Management Certificate

This is to certify that the company

Oertli Instrumente AG

Hafnerwisenstrasse 4
9442 Berneck
Switzerland

SRN: CH-MF-000016175

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	244057 MDR2017Q
Certificate ID	1000169504
Effective date	2024-06-06
Expiry date	2027-12-14
Frankfurt am Main,	2024-06-06

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

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Annex to EU Quality Management Certificate
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Authorised Representative of the company:

Oertli Ophthalmedic Östereich GmbH
Schwefel 93
6850 Dornbirn
AUSTRIA

SRN: AT-AR-000003554

Device categories and variants covered by this certificate:

Device category:	**MDA 0309 - Phacoemulsification/vitrectomy system**
Product name:	OS4 Ophthalmic Surgery System
Risk classification:	IIb
Basic-UDI-DI:	7630003MD110508UU
Intended purpose:	The full assembly of the device variant "anterior/posterior with endolaser", it includes the following functionalities: – Irrigation and aspiration (I/A function) – Ultrasound phaco (PHACO function) – Bipolar diathermy for coagulation in the case of bleeding and coaptation of the conjunctiva during the eye surgery (DIA function) – Bipolar diathermic capsulotomy (CAPS function) – Bipolar diathermic deep sclerotomy ab interno (HFDS GLAU function) – Operation of a vitrectomy instrument (VIT function) – Injection and extraction of viscoelastic substances (INJECTION and EXTRACTION functions) – Retinal photocoagulation with endolaser (LASER function) – Intraocular illumination (LUM function) – Maintaining intra-ocular pressure by air (AIR function) and active infusion (GFI function, gas-forced infusion) – Fluid/air exchange

Device category:	**MDA 0309 - Phacoemulsification/vitrectomy system**
Product name:	Faros Ophthalmic Surgery System
Risk classification:	IIb
Basic-UDI-DI:	7630003MD110503UJ
Intended purpose:	The full-feature surgery system “anterior/posterior” includes the following functions: – Irrigation and aspiration (I/A function) – Ultrasound phaco (PHACO function) – Bipolar diathermy for coagulation of bleeding and coaptation of conjunctiva during eye surgery (DIA function) – Bipolar diathermic capsulotomy (CAPS function) – Bipolar diathermic deep sclerotomy ab interno (HFDS GLAU function) – Operation of a vitrectomy instrument (VIT function) – Injection and extraction of viscoelastic substances (INJECT and EXTR function) – Intra-ocular illumination (LUM function) – Air toning of the eye (AIR function) or active infusion (GFI function, gas-forced infusion)

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Device category:	**MDA 0309 - Phacoemulsification system**
Product name:	CataRhex 3 Ophthalmic Surgery System
Risk classification:	IIb
Basic-UDI-DI:	7630003MD110507US
Intended purpose:	CataRhex 3 is used for surgical interventions in the anterior eye segment. – Irrigation and aspiration (I/A function) – Phacoemulsification (PHACO function) – Bipolar diathermy for the coagulation and coaptation of tissues and vessels during surgery (DIA function) – Bipolar diathermic capsulotomy (CAPS function) – Bipolar diathermic ab interno deep sclerotomy (HFDS function) – Operation of a vitrectomy cutter for anterior vitrectomy (VIT function)

Device category:	**MDA 0309 - Phacoemulsification system handpiece, reusable**
Product name:	Phaco Handpieces Reusable
Risk classification:	IIb
Basic-UDI-DI:	7630003MD0105111RR
Intended purpose:	The phacoemulsification (phaco) handpiece is intended for emulsifying lens and aspirating lens fragments and fluids, with optional simultaneous supply of irrigation fluid to maintain the intraocular pressure during surgical procedures in the anterior or posterior eye segment.

Device category:	**MDA 0309 - Open-surgery electrosurgical handpiece/electrode, bipolar, reusable**
Product name:	Diathermy Tips Reusable
Risk classification:	IIb
Basic-UDI-DI:	7630003MD00105122RW
Intended purpose:	The product is intended to be used for coagulation and coaptation of tissue and vessels in opthalmic surgery.

Device category:	**MDA 0309 - Open-surgery electrosurgical handpiece/electrode, bipolar, reusable**
Product name:	HFDS Tips Reusable
Risk classification:	IIb
Basic-UDI-DI:	7630003MD0105138SD
Intended purpose:	The product is intended to be used for a bipolar diathermal ab-interno deep sclerotomy.

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Device category:	**MDA 0309 - Open-surgery electrosurgical handpiece/electrode, bipolar, reusable**
Product name:	Capsulotomy Tips Reusable
Risk classification:	IIb
Basic-UDI-DI:	7630003MD0105137SB
Intended purpose:	The product is intended to be used for bipolar diathermal capsulotomy.

Device category:	**MDA 0309 - Open-surgery electrosurgical handpiece/electrode, bipolar, reusable**
Product name:	Endo Diathermy Tips Reusable
Risk classification:	IIb
Basic-UDI-DI:	7630003MD0105136S9
Intended purpose:	The product is intended to be used for coagulation and coaptation of tissue and vessels in ophthalmic surgery.

Device category:	**MDA 0309 - Open-surgery electrosurgical handpiece/electrode, bipolar, reusable**
Product name:	Diathermy Forceps Tips Reusable
Risk classification:	IIb
Basic-UDI-DI:	7630003MD0105135S7
Intended purpose:	The product is intended to be used for coagulation and coaptation of tissue and vessels in ophthalmic surgery.

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Device category:	**MDA 0309 - Open-surgery electrosurgical handpiece/electrode, bipolar, reusable**
Product name:	HF-Surgical Handpieces Reusable
Risk classification:	IIb
Basic-UDI-DI:	7630003MD0105112RT
Intended purpose:	The product is intended to be used for bipolar diathermy applications in ophthalmic surgery.

Device category:	**MDN 1206 - Ophthalmic cannulation set, single-use**
Product name:	Trocar System Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010551UG
Intended purpose:	The product is intended to be used for providing access at the pars plana to the posterior eye segment for ophthalmic procedures.

Device category:	**MDN1206 - Ophthalmic infusion/aspiration cannula, reusable**
Product name:	I/A Instruments Reusable
Risk classification:	IIa
Basic-UDI-DI:	7630003MD0105113RV
Intended purpose:	The irrigation and aspiration (I/A) handpieces are used in anterior segment eye surgery to aspirate tissues, cortical lens material or fluid substances and maintain chamber stability with irrigation fluid while aspirating.

Device category:	**MDN 1206 - Ophthalmic infusion/aspiration cannula, reusable**
Product name:	I/A Coaxial Handpieces Reusable
Risk classification:	IIa
Basic-UDI-DI:	7630003MD0105115RZ
Intended purpose:	The irrigation and aspiration (I/A) handpieces are used in anterior segment eye surgery to aspirate tissues, cortical lens material or fluid substances and maintain chamber stability with irrigation fluid while aspirating.

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Device category:	**MDN 1206 - Ophthalmic infusion/aspiration cannula, reusable**
Product name:	I/A Tips Reusable
Risk classification:	IIa
Basic-UDI-DI:	7630003MD0105123RY
Intended purpose:	The irrigation and aspiration (I/A) handpieces are used in anterior segment eye surgery to aspirate tissues, cortical lens material or fluid substances and maintain chamber stability with irrigation fluid while aspirating.

Device category:	**MDN 1206 - Ophthalmic infusion/aspiration cannula, single-use**
Product name:	I/A Instruments Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010531UA
Intended purpose:	The irrigation and aspiration (I/A) handpieces are used in anterior segment eye surgery to aspirate tissues, cortical lens material or fluid substances and maintain chamber stability with irrigation fluid while aspirating.

Device category:	**MDN1206 - Opthalmic surgical procedure kit, non-medicated, single-use**
Product name:	Surgery Packs single use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010512U6 7630003MD010513U8 7630003MD010516UE 7630003MD010517UG
Intended purpose:	Configuration Packs for use with Oertli Surgery units for cataract or vitractomy surgeries.

Device category:	**MDN 1206 - Opthalmic fiberoptic light instrument, single-use**
Product name:	Endo Illuminator Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010561UK
Intended purpose:	The product is intended to be used for intraocular illumination in vitreoretinal surgery.

Device category:	**MDN 1206 - Opthalmic fiberoptic light instrument, single-use**
Product name:	Transscleral Illuminator Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010565UT
Intended purpose:	The product is intended to be used for indenting and intraocular illumination through the sclera in procedures in the posterior eye segment.

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Device category:	**MDN 1206 - Opthalmic surgical procedure kit, non-medicated, single-use**
Product name:	Active Infusion Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010575UW
Intended purpose:	The product is intended to be used for compressed air controlled infusion of ophthalmic irrigation solution in ophthalmological procedures.

Device category:	**MDN 1206 - Phacoemulsification system handpiece tip, reusable**
Product name:	Phaco Tips Reusable
Risk classification:	IIa
Basic-UDI-DI:	7630003MD0105121RU
Intended purpose:	The phacoemulsification tips (phaco tips) are intended for emulsifying lens as well as aspirating lens fragments and fluids during surgical procedures in the anterior eye segment

Device category:	**MDN 1206 - Phacoemulsification system handpiece tip, reusable**
Product name:	Sleeves Reusable
Risk classification:	IIa
Basic-UDI-DI:	7630003MD0105124S2
Intended purpose:	The sleeves are intended for supplying of irrigation fluid to maintain the intraocular pressure as well as protecting of tissue at the incision against friction and heat of the phacoemulsification tip during surgical procedures in the anterior eye segment.

Device category:	**MDN 1206 - Phacoemulsification system handpiece tip, reusable**
Product name:	Endo Phaco Tips Reusable
Risk classification:	IIa
Basic-UDI-DI:	7630003MD0105126S6
Intended purpose:	The phacoemulsification tips (phaco tips) are intended for emulsifying lens as well as aspirating lens fragments and fluids during surgical procedures in the posterior eye segment.

Device category:	**MDN 1206 - Phacoemulsification system handpiece tip, single-use**
Product name:	Phaco Tips Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010521U7
Intended purpose:	The phacoemulsification tips (phaco tips) are intended for emulsifying lens as well as aspirating lens fragments and fluids during surgical procedures in the anterior eye segment.

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Device category:	**MDN 1206 - Phacoemulsification system handpiece tip, single-use**
Product name:	Sleeves Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010522U9
Intended purpose:	The sleeves are intended for supplying of irrigation fluid to maintain the intraocular pressure as well as protecting of tissue at the incision against friction and heat of the phacoemulsification tip during surgical procedures in the anterior eye segment.

Device category:	**MDN 1206 - Surgical irrigation/aspiration tubing set**
Product name:	Tubing Sets Single Pump System Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010502U3
Intended purpose:	I/A tubing system intended for use together with the surgical systems Faros, CataRhex 3 and CataRhex SwissTech. Suction and rinsing device for all surgical applications.

Device category:	**MDA 1206 - Surgical irrigation/aspiration tubing set**
Product name:	Tubing-Sets-Single-Pump-System-Reusable
Risk classification:	IIa
Basic-UDI-DI:	7630003MD0105102RQ
Intended purpose:	I/A tubing system intended for use together with the surgical systems Faros, CataRhex 3 and CataRhex SwissTech. Suction and rinsing device for all surgical applications.

Device category:	**MDN 1206 - Surgical irrigation/aspiration tubing set**
Product name:	Tubing Sets Daypack Single Pump System Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010504U7
Intended purpose:	I/A tubing system intended for use together with the surgical systems Faros, CataRhex 3 and CataRhex SwissTech. Suction and rinsing device for all surgical applications.

Device category:	**MDN 1206 - Surgical irrigation/aspiration tubing set**
Product name:	Tubing Sets Dual Pump System Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010503U5
Intended purpose:	Cassette containing I/A tubes intended for use together with the OS4 operation system (VC860100, VC860200, VC860300). Irrigation and aspiration device for all surgical applications.

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Device category:	**MDN 1206 - Surgical irrigation/aspiration tubing set**
Product name:	Infusion Set Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010509UH
Intended purpose:	The product is intended to be used for infusion of ophthalmic irrigation solutions to maintain the intraocular pressure, during surgical procedures in the anterior and posterior eye segment.

Device category:	**MDN 1206 - Surgical irrigation/aspiration tubing set**
Product name:	Air Delivery Lines Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010574UU
Intended purpose:	The product is intended to be used for the switchable liquid and gas supply in ophthalmological procedures in the posterior eye segment.

Device category:	**MDN 1206 - Vitrectomy system micro-cutting unit**
Product name:	Vitrectomy Cutter Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010542UF
Intended purpose:	The product is intended to be used for cutting and removal of vitreous body and tissue and for the aspiration of liquids and gases during surgical procedures in the anterior and posterior segments of the eye.

Device category:	**MDN1206 - Vitreoretinal tamponade tubing**
Product name:	Visco Instruments Single Use
Risk classification:	IIa
Basic-UDI-DI:	7630003MD010573US
Intended purpose:	The instrument is intended for the injection and extraction of viscous fluid during posterior segment eye surgery.

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Examinations and tests performed:
244057_A210070MED_01 dated 2022-12-04
244057_A210070MED_01_CataRhex3 dated 2022-11-17
244057_A210070MED_02_Phaco Instruments Reusable dated 2022-10-28
244057_A210070MED_03_Vitrectomy Cutter Single Use dated 2022-12-09

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-12-15	170780307	Summary of the device category
02	2023-03-23	170783415	New certificate template and new Authorised Representative