EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Oertli Instrumente AG

Hafnerwisenstrasse 4
9442 Berneck
Switzerland

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Modular and integrated ophthalmologic surgical systems, sterile equipment for ophthamologic surgical systems and reusable equipment for ophthamologic surgical systems according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	244057 MR2
Certificate unique ID	170760259
Effective date	2019-12-23
Expiry date	2023-11-11
Frankfurt am Main	2019-12-23

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 244057 MR2
Certificate unique ID: 170760259
Effective date: 2019-12-23

Oertli Instrumente AG

Hafnerwisenstrasse 4
9442 Berneck
Switzerland

Device family	Device	Class
Ophthalmic surgical systems	Faros	IIb
	CataRhex 3	IIb
	OS4	IIb
Sterile equipment for ophthalmic surgical systems	Tubing Sets OS3, Single Use	IIa
	Tubing Sets Faros CataRhex Family Single Use	IIa
	Tubing Sets OS4 Single Use	IIa
	Tubing Sets Daypack OS3 Faros CataRhex Single Use	IIa
	Surgery Packs Twin Vac OS3 Single Use	IIa
	Surgery Packs Faros CataRhex Family Single Use	IIa
	Surgery Packs OS4 Single Use	IIa
	Vitrectomy Packs OS3 Single Use	IIa
	Vitrectomy Packs Faros Single Use	IIa
	Vitrectomy Packs OS4 Single Use	IIa
	Surgery Packs Combined Single Use	IIa
	Phaco Tips Single Use	IIa
	Sleeves Single Use	IIa
	I/A Instruments Single Use	IIa
	SUS Cutting Heads Single Use	IIa
	Vitrectomy Cutter Single Use	IIa
	PMS Parsplana Microincision Systems Single Use	IIa/Is
	Endo Illuminator Single Use	IIa
	Transscleral Illuminator Single Use	IIa
	Active Infusion Single Use	IIa
	Air Visco Instruments Single Use	IIa
	Air Delivery Lines Single Use	IIa
	Active Infusion Set OS4 Single Use	IIa
Reusable equipment for ophthalmic surgical systems	Tubing Sets OS3 Reusable	IIa
	Tubing Sets Faros CataRhex Family Reusable	IIa
	Phaco Instruments Reusable	IIb
	Diathermy Instruments Reusable	IIb
	I/A Instruments Reusable	IIa
	Cutting Instruments Reusable	IIb
	Phaco Tips Reusable	IIa
	Diathermy Tips Reusable	IIb
	I/A Tips Reusable	IIa
	Sleeves Reusable	IIa
	Vitrectomy Accessories Reusable	IIa