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	170770924
Effective date	2020-10-19
Expiry date	2024-05-26
Frankfurt am Main	2020-10-19

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
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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: 170770924
Effective date: 2020-10-19

Oertli Instrumente AG

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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

Oertli Instrumente AG
Hafnerwisenstrasse 4
9442 Berneck
Switzerland

Our ref.: NA, Phone: 069 95427-263, Fax: -388
E-Mail: anya.bleker@dqs-med.de

Frankfurt a. M.
2021-12-28

Certification confirmation letter

To whom it may concern,

DQS Medizinprodukte GmbH is a Notified Body according to § 15 Medical Devices Act – Directive 93/42/EEC and according to Regulation (EU) 2017/745 on medical devices. After 25th May 2021, Regulation (EU) 2017/745 superseded Directive 93/42/EEC.
We as a Notified Body will continue to perform the surveillance activities for certificates according to Directive 93/42/EEC issued by DQS Medizinprodukte GmbH, which are still valid.
DQS Medizinprodukte GmbH is registered as NB 0297.

Furthermore, DQS Medizinprodukte GmbH is an accredited certification body for management systems under the terms of DIN EN ISO/IEC 17021-1:2015 to carry out certifications of management systems according to DIN EN ISO 13485:2016.

DQS Medizinprodukte GmbH hereby confirms that the EC-Certificate (Certificate registration no. 244057MR2 with the unique certification ID 170770924 valid from 2020-10-19 until 2024-05-26) has been issued to the following auditee:

Oertli Instrumente AG
Hafnerwisenstrasse 4
9442 Berneck
Switzerland

in accordance with Annex II excluding section 4 of Council Directive 93/42/EEC concerning medical devices.

The following product has been terminated as of 13.10.2021 and is no longer valid on the current certificate (170770924):

Device Family	Device	Class
Reusable equipment for ophthalmic surgical systems	**Cutting Instruments Reusable**	**IIb**

Yours faithfully,
DQS Medizinprodukte GmbH

i.A. Stefan Bellmann
Regulatory Affairs Manager

Oertli Instrumente AG
Hafnerwisenstrasse 4
9442 Berneck
Switzerland

Our ref.: NA, Phone: 069 95427-263, Fax: -388
E-Mail: anya.bleker@dqs-med.de

Frankfurt a. M.
2022-04-27

Certification confirmation letter

To whom it may concern,

DQS Medizinprodukte GmbH is a Notified Body according to § 15 Medical Devices Act – Directive 93/42/EEC and according to Regulation (EU) 2017/745 on medical devices. After 25th May 2021, Regulation (EU) 2017/745 superseded Directive 93/42/EEC.
We as a Notified Body will continue to perform the surveillance activities for certificates according to Directive 93/42/EEC issued by DQS Medizinprodukte GmbH, which are still valid.
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DQS Medizinprodukte GmbH hereby confirms that the EC-Certificate (Certificate registration no. 244057MR2 with the unique certification ID 170770924 valid from 2020-10-19 until 2024-05-26) has been issued to the following auditee:

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in accordance with Annex II excluding section 4 of Council Directive 93/42/EEC concerning medical devices.

The following product has been terminated as of 22.04.2022 and is no longer valid on the current certificate (170770924):

Device Family	Device	Class
Sterile equipment for ophthalmic surgical systems	**SUS Cutting Heads Single Use**	**IIa**

Further, as of 22.04.2022, the name of “PMS Parsplana Microincision System Single Use" class IIa / Is has been changed to “Caliburn Trocar System Single Use" class IIa / Is.

Yours faithfully,
DQS Medizinprodukte GmbH

i.A. Natalie Wimmer
Regulatory Affairs Manager