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Declaration of Conformity

European medical device regulation (EU) 2017/745

Berneck, 7 November 2024

We hereby declare, on our sole responsibility, that the medical devices

Product	**MD1105.03** **Faros Ophthalmic Surgery System**
Reference number	**VC840100, VC840101 and corresponding pedal: VE830011**
Classification	**IIb, according to annex VIII of the regulation MDR (EU) 2017/745**
Device category	**MDA 0309 – Phacoemulsification/vitrectomy system**
Basic UDI-DI	**7630003MD110503UJ**
Manufacturer	Oertli Instrumente AG, Hafnerwisenstrasse 4, 9442 Berneck, Switzerland
SRN	CH-MF-000016175
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)

meet the applicable provisions, in particular the General Safety and Performance Requirements of the regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

Oertli Instrumente AG
Hafnerwisenstrasse 4
9442 Berneck
Switzerland

T +41 71 747 42 00
F +41 71 747 42 90
www.oertli-instruments.com

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The Conformity Assessment Procedure according to MDR (EU) Annex IX, Chapter I, III and Section 4 has been performed and the Notified Body has evaluated the Technical Documentation according to Annex II and Annex III.

EC-Certificate, Certificate registration no.:	**244057 MDR2017Q**
Notified Body:	**DQS Medizinprodukte GmbH, August-Schanz-Strasse 21 60433 Frankfurt am Main, Deutschland**
Identification number notified body:	**0297**
EC-Representative:	**Oertli Ophthalmedic Österreich GmbH, Schwefel 93, 6850 Dornbirn, Austria SRN: AT-AR-000003554**
Other relevant Union legislations	**RoHS Directive 2011/65/E**
This certificate is valid until	14.12.2027

Oertli Instrumente AG

Norbert Brill
Person Responsible for Regulatory Compliance
Head of Research and Development
Executive Board Member

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Oertli Instrumente AG
Hafnerwisenstrasse 4
9442 Berneck
Switzerland
T +41 71 747 42 00
F +41 71 747 42 90
www.oertli-instruments.com