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SWITZERLAND

Declaration of Conformity

European medical device regulation (EU) 2017/745

Berneck, 8 November 2024

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

Product	**MD0105.111** **Phaco Handpieces Reusable**
Reference number	**VG800011**
Classification	**IIb, according to annex VIII of the regulation MDR (EU) 2017/745**
Device category	**MDN 0309 – Phacoemulsification system handpiece, reusable**
Basic UDI-DI	**7630003MD0105111RR**
Manufacturer	Oertli Instrumente AG, Hafnerwisenstrasse 4, 9442 Berneck, Switzerland
SRN	CH-MF-000016175
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.

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.

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**

Template QMF 04.14, rev. 22.10.2024

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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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