



CERTIFICATE



This is to certify that the company

Oertli Instrumente AG

Hafnerwissenstrasse 4
9442 Berneck
Switzerland

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:

Design and development, manufacture, distribution and services of surgical systems, lens removal devices and vitrectomy devices and accessories, HF surgical devices and accessoires sterile equipment for the area of ophthalmology.

-AUS (a), BRA, USA (a,b,c,d)

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

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	244057 MDSAP16
Certificate unique ID	170770926
Effective date	2020-10-19
Expiry date	2023-10-18
Frankfurt am Main	2020-10-19



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

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

DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



Annex to certificate
Certificate registration No.: 244057 MDSAP16
Certificate unique ID: 170770926
Effective date: 2020-10-19



Oertli Instrumente AG

Hafnerwissenstrasse 4
9442 Berneck
Switzerland

Audited site

Oertli Instrumente AG
Hafnerwissenstrasse 4
9442 Berneck
Switzerland

DUNS No., site scope and country-specific requirements

Design and development, manufacture,
distribution and services of surgical systems,
lens removal devices and vitrectomy devices
and accessories, HF surgical devices and
accessoires sterile equipment for the area of
ophthalmology.
-AUS (a), BRA, USA (a,b,c,d)
DUNS No.: 481505238



Annex to certificate
Certificate registration No.: 244057 MDSAP16
Certificate unique ID: 170770926
Effective date: 2020-10-19

Oertli Instrumente AG

Hafnerwissenstrasse 4
9442 Berneck
Switzerland

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821