

Certificate US20/819943818

The quality management system of

# Ocular Instruments, Inc.

2255 116<sup>th</sup> Avenue NE, Bellevue, WA, 98004, United States Of America  
Facility number: F002683

has been assessed and certified as meeting the requirements of

## **MDSAP (ISO 13485:2016)**

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021 - Field Actions; RDC ANVISA n. 67/2009 - Vigilance

Canada: Medical Device Regulations (SOR/98-282) Part 1 - General

Japan: Japan PMD Act (as applicable), MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 60 (2021)

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design, Manufacture, Distribution and Service of Ophthalmic Instruments, Diagnostic Lenses, Indirect Lenses, Laser Lenses, Sterile Contact Ophthalmic Lenses, Surgical Lenses, and Tonometers for Ophthalmic procedures.

This certificate is valid from Effective date 2025-08-29 until Expiry date 2028-08-29 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 2020-02-28

Certified activities performed by additional sites are listed on subsequent pages.



Authorised by

Lynn Henderson

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - [www.sgs.com](http://www.sgs.com)

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at [www.SGS.com](http://www.SGS.com).



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



Certificate US20/819943818, continued  
**Ocular Instruments, Inc.**

**SGS**

**MDSAP (ISO 13485:2016)**

Issue 4

**Sites**

Ocular Instruments, Inc.  
2255 116<sup>th</sup> Avenue NE, Bellevue, WA, 98004, United States Of America  
Facility number: F002683

Design, Manufacture, Distribution and Service of Ophthalmic Instruments, Diagnostic Lenses, Indirect Lenses, Laser Lenses, Sterile Contact Ophthalmic Lenses, Surgical Lenses, and Tonometers for Ophthalmic procedures.

Ocular Instruments, Inc.  
1500 W. Dolarway, Building 9, Ellensburg, WA 98926, United States of America  
Facility number: F008288

Manufacture and Storage of Ophthalmic Instrument sub-parts in support of Ophthalmic Instruments, Diagnostic Lenses, Indirect Lenses, Laser Lenses, Sterile Contact Ophthalmic Lenses, Surgical Lenses, and Tonometers.



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

