

Certificate Number US20/819943818
The management system of

Ocular Instruments, Inc.

2255 116th Avenue NE, Bellevue, WA, 98004, United States

Dun & Bradstreet D-U-N-S identification number : 04-621-2387

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP (ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /RDC ANVISA n. 67/2009

Canada:
Medical Devices Regulations – Part 1 SOR 98/282

Japan:
MHLW Ministerial Ordinance 169 /Article 4 to Article 68 / PMD Act

United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

See second page for the scope.

The certificate is valid from
Effective Date: 2021-07-27 until Expiry Date: 2023-02-27
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2022-06-21
Issue 2. Certified since 2020-02-28



Authorised by L Henderson
Business Manager



L. Henderson

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MDSAP M2

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Certificate Number US20/819943818, continued

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Ocular Instruments, Inc.

MDSAP (ISO 13485:2016)

Issue 2



Detailed scope

Design, manufacture, and service of laser, sterile and non-sterile surgical, and diagnostic lenses and tonometers for ophthalmic procedures.

Additional facilities

13600 NE 20th Street, Suite F, Bellevue, WA, 98005, United States

