

Certificate Number US19/819943362

The quality management system of



OCULO-PLASTIK, INC.

200 West Sauvé Street, Montréal, Quebec, H3L 1Y9, Canada

Dun & Bradstreet D-U-N-S identification number : 25-738-2580

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)

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

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



For the following activities and devices

Design, Manufacture of non sterile ophthalmic implants, conformers for ophthalmic surgery; and ocular shields for general and laser surgeries.

Conception, fabrication d'implants ophtalmiques non stériles, conformateurs non stériles utilisés en chirurgie ophtalmique et protecteurs oculaires non stériles utilisés pour chirurgies laser et générale.

This certificate is valid from
Effective Date: 2019-09-12 until Expiry Date: 2022-09-11
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2022-01-31
Issue 1. Certified since 2019-09-12

Authorised by J Hall
Business Manager

SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS United Kingdom Ltd is an MDSAP authorised auditing organization

SGS MDSAP 1116

Page 1 of 1



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.