

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

PSI/EYE-KO, Inc.  
also doing business as Anodyne Surgical  
804 Corporate Centre Drive  
O'Fallon  
Missouri  
63368  
USA

Facility ID Number: F003393

Holds Certificate No:

**MDSAP 705814**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, manufacture and distribution of sterile and non-sterile disposable cannulas and disposable handheld surgical instruments for Ophthalmology. The service of reusable surgical instruments for Ophthalmology.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-02-27

Effective Date: 2024-02-27

Expiry Date: 2027-02-26



BSI Group America Inc. is an MDSAP recognised auditing organization