



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate No:

FM 35007

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The manufacture and distribution of sterile and non-sterile disposable cannulas and disposable hand held surgical instruments for ophthalmology.

For and on behalf of BSI:

SM SI

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 1996-09-25 Latest Revision Date: 2019-05-15

bsi.



Effective Date: 2018-11-20

Expiry Date: 2021-11-19

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...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.