

## Production Quality Assurance

No. CE 01626



Issued to:

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

In respect of:

The manufacture of sterile and non-sterile disposable cannulas and disposable hand held surgical instruments for Ophthalmology

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: 4 Jun 1997

Date: 16 May 2012

Expiration Date: 3 Jun 2017

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### Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate unless specifically agreed with BSI.

*raising standards worldwide™*



**Information and Contact:** BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000

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