



Production Quality Assurance

No. CE 01626

Issued to:

PSI/EYE-KO INC
804 Corporate Centre Drive
O' Fallon
MO 63368
Missouri
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 the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

Alastair Trivett, Managing Director, BSI Product Services – Global

First Issued: 4 Jun 1997

Date: 5 Jun 2007

Expiration Date: 4 Jun 2012

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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.

EC Certificate

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No. **CE 01626**
Date: **5 Jun 2007**
Issued to: **PSI/EYE-KO INC**
MO 63368
USA

Subcontractor

Service(s) supplied

STERIS Isomedix Services, Inc.
North Facility
1880 Industrial Drive
Libertyville
IL 60048
USA

Sterilization

History of Quality Assurance Certificate

Certificate No: CE 01626
Issue Date: 5 Jun 2007
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Date	Action
04 June 1997	Issue Annex V certificate
05 June 1998	Reissue of certificate after location change
08 May 2000	Reissue of certificate after street name change
11 August 2004	Reissue of certificate in new format and certificate renewal
27 September 2006	Reissue of certificate due to city name change from St. Charles to O'Fallon
05 June 2007	5 Year Renewal. Amendment of subcontractor name from Steris Corp/Isomedix to STERIS Isomedix Services, Inc.