

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

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 of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

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



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **04 June 1997**Date: **11 April 2017**Expiry Date: **03 June 2022**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. 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.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

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

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O'Fallon
Missouri
63368
USA

Subcontractor:

Service(s) supplied

SD Healthcare
10 Wharfside Business Park
Irlam Wharf Road
Irlam
Manchester M44 5PN
United Kingdom

EU Representative

STERIS Isomedix Services
2500 Commerce Drive
Libertyville
IL 60048
USA

Sterilization

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	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	4607220	Reissue of certificate in new format and certificate renewal.
27 September 2006	4860695	Reissue of certificate due to city name change from St. Charles to O'Fallon.
05 June 2007	7019758	5 Year Renewal. Amendment of subcontractor name from Steris Corp/Isomedix to STERIS Isomedix Services, Inc.
26 January 2011	7632666	Addition of 'PSI/EYE-KO, Inc. dba Anodyne Surgical', 'PSI/EYEKO, Inco dba Assurance Products' and 'PSIIEYE-KO, Inc. dba PoSo!.' to certificate address. Addition of Surgical Design UK Ltd as EU representative. Correction of Steris Isomedix address.
25 August 2011	7728764	Removal of 'Surgical Design UK Ltd, Manchester' as EU Representative and replaced with 'SO Healthcare, Manchester'.

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Date	Reference Number	Action
16 May 2012	7829286	Certificate Renewal.
11 April 2017	8698087	Certificate Renewal.

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