By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 01626**

Issued To: **PSI/EYE-KO, Inc. dba Anodyne Surgical**
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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1997-06-04** Date: **2021-05-25** Expiry Date: **2022-06-03**

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Supplementary Information to CE 01626

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Device code	Device name	Intended purpose per IFU
Class IIa		
MD 0105	Cannulas and hand held instruments for Ophthalmology	---

First Issued: **1997-06-04** Date: **2021-05-25** Expiry Date: **2022-06-03**

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List of Significant Subcontractors

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

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Subcontractor:	**Service(s) supplied**
Advena Ltd Tower Business Centre 2nd Floor, Tower Street Swatar BKR 4013 Malta	**EU Representative**
Steris Isomedix Services 2500 Commerce Drive Libertyville Illinois 60048 USA	**Radiation (Gamma 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.
20 February 2019	7781199	Traceable to NB 0086. Administrative change to ‚STERIS Isomedix Services' from ‚Sterilization' to ‚Gamma Sterilization.
01 July 2019	9680066	Change of the company name from: PSI/EYE-KO, Inc. PSI/ EYE-KO, Inc. Dba Anodyne Surgical PSI/ EYE-KO, Inc. Assurance Products PSI/ EYE-KO, Inc.dba P.S.I To: PSI/ EYE-KO, Inc. Dba Anodyne Surgical Change of EU rep from SD Healthcare, Manchester M44 SPN, UK to Surgitrac Europe S.A.S, Rennes, France.
Current	3430556	Update of Certificate with new EU Rep Advena Ltd. Addition of a device table.