By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 59279**

Issued To: **Volk Optical Inc**
7893 Enterprise Drive
Mentor
Ohio
44060
USA

In respect of:

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of single use ophthalmic lenses for diagnostic examinations and for use in the therapy of intraocular abnormalities.

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):

Albert Roossien, Regulatory Lead

First Issued: **2001-06-29** Date: **2019-02-14** Expiry Date: **2021-03-29**

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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**
Keeler Ltd. Clewer Hill Road Windsor Berkshire SL4 4AA United Kingdom	**EU Representative**
STERIS Isomedix Services 380 90th Avenue NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
29 June 2001		First issue.
08 April 2005	4670846	Extension of scope to include sterile, single use vitrectomy ophthalmic lenses. Addition of First Engineering Optics PTE LTD as lenses manufacturing subcontractor and Centurion Sterilization Services as ETO Sterilization, Packaging and Testing subcontractor.
31 May 2006	4828172	Certificate renewal.
19 March 2008	7183955	Change of name of significant subcontractor 'First Engineering Optics Pte Ltd, First Engineering Techno Centre' to 'First Engineering Plastics Pte Ltd.'
26 May 2011	7650551	Addition of Keeler Limited as EU representative. Removal of Retinal Scales from scope. Removal of First Engineering Plastics (Malaysia) SDN BHD as significant subcontractor. Certificate renewal.
21 March 2013	7970102	Removal of Centurion Sterilization Services and addition of Phakos as significant subcontractor.
26 January 2015	8283147	Addition of 'Steris Isomedix Services' as significant subcontractor.

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Date	Reference Number	Action
30 November 2015	8437736	Extension to scope to cover ophthalmic lenses for diagnostic examinations and for use in the therapy of intraocular abnormalities.
29 April 2016	8499729	Certificate renewal. Removal of Phakos as significant subcontractor.
Current	7781217	Traceable to NB 0086.