

# EC Certificate - Production Quality Assurance

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

## List of Significant Subcontractors

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

Certificate No: **CE 59279**  
 Date: **29 April 2016**  
 Issued To: **Volk Optical Inc**  
**7893 Enterprise Drive**  
**Mentor**  
**Ohio**  
**44060**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Keeler Limited Clewer Hill Road Windsor Berkshire SL4 4AA United Kingdom	<b>EU Representative</b>
Steris Isomedix Services 380 90th Avenue NW Minneapolis Minnesota 55433 USA	<b>ETO Sterilization</b>

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## 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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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000  
 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
 A member of BSI Group of Companies.



By Royal Charter

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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.

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