Certificate

Full Quality Assurance

No. CE 01801

Issued to:

Lenstec (Barbados) Inc
Airport Commercial Centre
Pilgrim Road
Christ Church
Barbados

In respect of:

The design and manufacture of sterile HEMA, Silicone and PMMA anterior and posterior chamber intra-ocular lenses, sterile capsular tension rings, sterile viscoelastic solutions for use in ophthalmic surgery, injector cartridges and systems

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

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

David Ford, Director, Healthcare and Testing Services

First Issued: **24 Dec 1997** Date: **20 Aug 2009**

Expiration Date: **6 Jul 2013**

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.

Certificate

List of Significant Subcontractors

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

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Subcontractor	Service(s) supplied
Lenstec Inc (Florida) 1765 Commerce Ave N St. Petersburg Florida 33716 USA	Design Sales Purchasing
Oasis Medical, Inc 510-528 S. Vermont Avenue Glendora CA 91741 USA	Manufacture Design
LA LABS 7334 Hollister Ave, Suite H. Goleta CA 93117 USA	Manufacture Design

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History of Quality Assurance Certificate

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Date	Reference Number	Action
24 December 1997		First Issued
21 January 1999		Addition of capsular tension rings to scope
19 April 1999		Addition of HEMA and PMMA to scope
14 June 2000		Addition of testing to scope
26 June 2001		Addition of silicone and sterile viscoelastic solutions for use in ophthalmic surgery to scope, Addition of Croma-Pharma GesmbH as a manufacture sub-contractor
09 July 2001		Removal of Croma-Pharma GesmbH as a manufacture sub-contractor
11 September 2002		Addition of Development and the removal of testing to scope, Addition of Croma-Pharma GesmbH as a manufacture sub-contractor, Addition of Thinoptx Inc as a design and manufacture sub-contractor.
10 February 2003		Reissue in new format, Addition of sterile reading implants for non-myopic individuals to scope, Addition of Lenstec Inc (Barbados) as a manufacture sterilisation sub-contractor.

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07 July 2003		Five year renewal
09 February 2006		Change of holder of certificate from Lenstec Inc to Lenstec Barbados Inc. Change to address. Change to scope to include 'chamber'. Removal of 'Sterile reading implants for Non-Myopic individuals.' Addition of 'injector cartridges and systems' to scope. Removal of subcontractors: Croma-Pharma GesmbH, ThinOptX and Lenstec Inc (Barbados). Addition of Oasis Medical and LA Labs as subcontractors for the design and manufacture of viscoelastics. Removal of 'manufacture' as a service supplied by Lenstec Inc (Florida) and addition of sales and purchasing. Reissue in new certificate format
23 May 2008	7202927	Certificate Renewal. Minor amendments to address
17 December 2008	7236937	Change to certificate address and addition of supplement information pages
20 August 2009	7378079	Removal of supplement information pages and change of address for subcontractor 'Lenstec Inc (Florida)'