EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01801**

Issued To: **Lenstec (Barbados) Inc.**
Airport Commercial Centre
Pilgrim Road
Christ Church
BB17092
Barbados

In respect of:

The design and manufacture of sterile anterior and posterior chamber intra-ocular lenses, sterile capsular tension rings and sterile injector cartridges and systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **1997-12-24** Date: **2021-03-01** Expiry Date: **2023-07-06**

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Supplementary Information to CE 01801

Issued To:

Lenstec (Barbados) Inc.
Airport Commercial Centre
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Number	Device Name	Intended purpose per IFU
Class IIb		
MDN 0204	Posterior-chamber Intraocular Lenses	Visual Correction of Aphakia
MDN 0204	Anterior-chamber Intraocular Lenses	Visual Correction of Aphakia
MDN 0204	Capsular Tension Rings	Stabilisation of the Capsular Bag
Class IIa		
MDN 0105	Intraocular Lens – Insertion Cartridge	Aid in the implantation of a foldable Intraocular Lens
MDN 0105	Intraocular Lens Injector, Single Use	Aid in the implantation of a foldable Intraocular Lens

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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**
CMI spol s.r.o Trencianska 47 821 09 Bratislava Slovakia	**EU Representative**
Lenstec Inc (Florida) 1765 Commerce Ave N St. Petersburg Florida 33716 USA	**Manufacture**

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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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Date	Reference Number	Action
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 amendment to address.
17 December 2008	7236937	Change to certificate address and addition of supplementary information pages.
20 August 2009	7378079	Removal of supplementary information pages and change of address for subcontractor 'Lenstec Inc (Florida)'.

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Date	Reference Number	Action
23 March 2012	7768699	Change of scope to remove viscoelastic solutions. Removal of Oasis Medical and LA Labs as significant subcontractors. Addition of Lenstec Barbados Inc, UK as European Representative.
16 April 2013	7982947	Certificate Renewal.
21 June 2016	8499765	Extension to scope to add intra-ocular lenses made from copolymer of PEA and PEMA.
28 June 2018	8936601	Certificate renewal. Removal of "design" from activities on Florida site (supplementary page). Removal of "sales and purchasing" from activities on Florida site (supplementary page). Addition of "manufacturing" as an activity for the Florida site (supplementary page).
12 February 2019	9733555	Traceable to NB 0086.
Current	3328235	Change of EU representative. Addition of Device table. Review of proprietary additional manufacturing step for IOL device.