

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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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.

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Supplementary Information to CE 01801

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**Lenstec (Barbados) Inc.
 Airport Commercial Centre
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 BB17092
 Barbados**

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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