By Royal Charter

# 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**

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System

**Supplementary Information to CE 01801**

Issued To:

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

First Issued: **1997-12-24** Date: **2021-03-01** Expiry Date: **2023-07-06**