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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

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
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**

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Lenstec (Barbados) Inc.
Airport Commercial Centre
Pilgrim Road
Christ Church
BB17092
Barbados
20th June 2024

Notified Body Confirmation Letter

Reference: EU2023-607/894471

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Lenstec (Barbados) Inc.
Airport Commercial Centre
Pilgrim Road
Christ Church
BB17092
Barbados

SRN Number (if available): BB-MF-000019262

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge

Graeme Tunbridge
Senior Vice President, Medical Devices

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SBL-2	Class IIb implantable non-WET	N/A	CE 01801, NB# 2797
SBL-2 Click	Class IIb implantable non-WET	N/A	CE 01801, NB# 2797
SBL-3	Class IIb implantable non-WET	N/A	CE 01801, NB# 2797
SBL-3 Click	Class IIb implantable non-WET	N/A	CE 01801, NB# 2797
Softec HDY	Class IIb implantable non-WET	N/A	CE 01801, NB# 2797
Softec HDY Click	Class IIb implantable non-WET	N/A	CE 01801, NB# 2797
LR-1300B	Class IIb implantable non-WET	N/A	CE 01801, NB# 2797
LR-1400B	Class IIb implantable non-WET	N/A	CE 01801, NB# 2797
Softec HP1	Class IIb implantable non-WET	N/A	CE 01801, NB# 2797
Softec HD3	Class IIb implantable non-WET	N/A	CE 01801, NB# 2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/06/20	Initial issue