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By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 756533 R000

Manufacturer: Lenstec (Barbados) Inc.

Address:
Airport Commercial Centre
Pilgrim Road
Christ Church
BB17092
Barbados

Single Registration Number: BB-MF-000019262

EU Authorised Representative: CMI spol s.r.o

Address:
Trencianska 47
821 09 Bratislava
Slovakia

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-06-08**

Current Issue Date: **2025-12-02**

Starting Validity Date: **2025-12-02**

Expiry Date: **2028-06-07**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Device Schedule: Class III and Class IIb devices

Class IIb, Implantable	Intended purpose
Softec I, Softec HD and Softec HD Click Intraocular Lenses	See MDR 756711
SBL-2, SBL-3, SBL-2 Click and SBL-3 Click Intraocular Lenses	See MDR 756698
Softec HDY and Softec HDY Click Intraocular Lenses	See MDR 756707
Softec HD3 Intraocular Lenses	See MDR 756710

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-06-08	3509067	Issued
Current	30534332	Supplemented – addition of SBL-2, SBL-3, Softec HDY and Softec HD3 Intraocular Lenses

Digitally signed by AVETISYAN ARMEN 2325020185
Date: 2026.11.10 17:10:20 AMT

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