

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

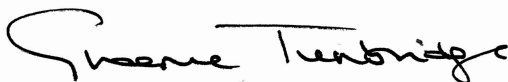
Address:

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 Medical Devices

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

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

Starting Validity Date: **2023-06-08**

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

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Device Schedule: Class III and Class IIb devices

Class IIb, Implantable	Intended purpose
Softec Intraocular Lenses	See MDR 756711



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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
Current	3509067	Issued



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