EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 756711 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 assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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:

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose	Risk Classification	Basic UDI-DI
Softec I	Softec I	MDN 1104	Optical implants intended for the replacement of the human crystalline lens following phacoemulsification cataract removal (Aphakia). The lenses are single-use only and indicated for capsular bag placement only.	Class IIb Implantable -non-WET	08443690SOFTECIWL
Softec HD	Softec HD	MDN 1104	Optical implants intended for the replacement of the human crystalline lens following phacoemulsification cataract removal (Aphakia). The lenses are single-use only and indicated for capsular bag placement only.	Class IIb Implantable -non-WET	08443690SOFTECHD8G
Softec HD Click	Softec HD Click	MDN 1104	Optical implants intended for the replacement of the human crystalline lens following phacoemulsification cataract removal (Aphakia). The lenses are single-use only and indicated for capsular bag placement only.	Class IIb Implantable -non-WET	08443690SOFTECHDCLICK5S

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Additional Information:

Softec I
Spherical equivalent power at IOL plane, -5.0D to +10.0D and +31.0D to +36.0D in 1.00D Increments
+10.5D to +30.0D in 0.50D Increments

Softec HD
Bi-aspheric equivalent power at IOL plane, +5.0D to +10.0D and +31.0D to +36.0D in 1.00D Increments, +10.5D to +14.5D and +25.5D to +30.0D in 0.50D Increments and +15.0D to +25.0D in 0.25D Increments.

Softec HD Click
Bi-aspheric equivalent power at IOL plane, +5.0D to +10.0D and +31.0D to +36.0D in 1.00D Increments, +10.5D to +14.5D and +25.5D to +30.0D in 0.50D Increments and +15.0D to +25.0D in 0.25D Increments.

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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	3510132	Issued

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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.

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