

# 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

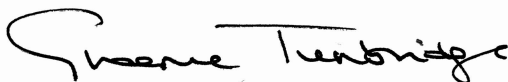
**Address:**

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

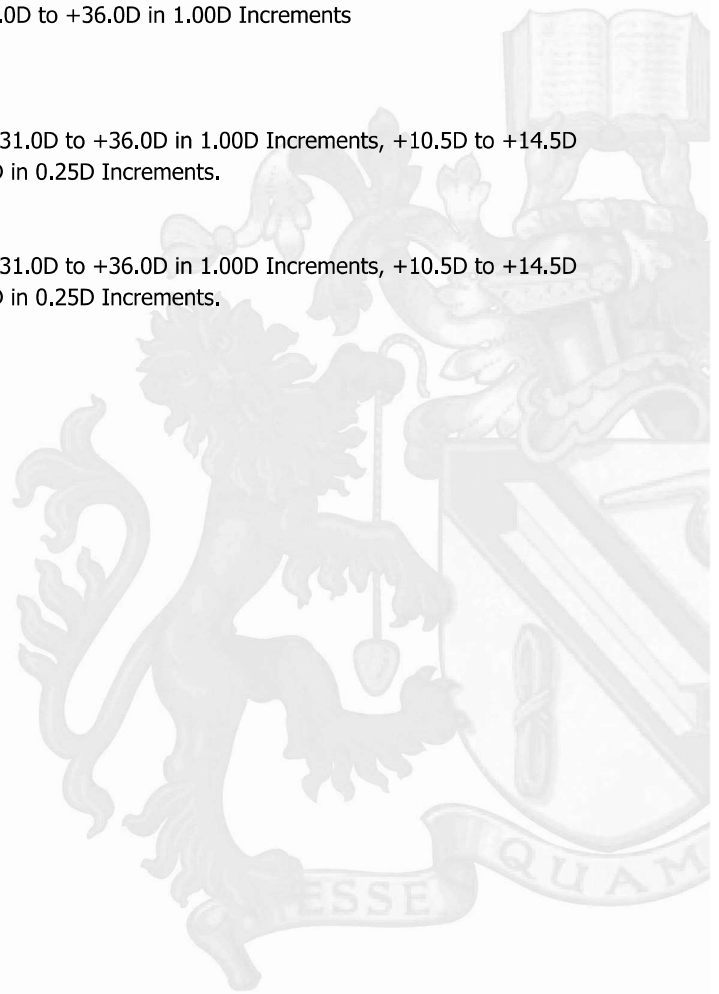
Spherical equivalent power at IOL plane, -5.0D to +10.0D and +31.0D to +36.0D in 1.00D Increments  
+10.5D to +30.0D in 0.50D Increments

#### 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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