LENSTEC (BARBADOS) INC.
Airport Commercial Centre, Pilgrim Road, Christ Church, BARBADOS 17092
Telephone: +1(246) 420-6795 • Fax: +1(246) 420-6797 • Email: lenstecbarbados@lenstec.com

EU – DECLARATION OF CONFORMITY

We **Lenstec (Barbados) Inc.** being the manufacturer and distributor within the European Economic Area of the medical device listed below, declare that this product is in conformity with the provisions of the **Medical Device Regulation 2017/745** and has been subject to the conformity procedures laid down in **Annex IX (Chapters I, II & III)** under the supervision of the British Standards Institution (BSI) Group The Netherlands B. V., a Notified Body designated by the Netherlands Competent Authority, and carrying the Notified Body Number 2797. Furthermore, we declare that we are certified ISO 13485 FM 38446 and have been allocated MDR 2017/745 CE certificates MDR 756533 R000 and MDR 756711 R000 for the listed product.

The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Design Name/Location
Lenstec Inc
1765 Commerce Ave. N
St. Petersburg, FL
33716, USA

Design/Manufacturing Name/Location
Lenstec (Barbados) Inc
Airport Commercial Centre
Pilgrim Road, Christ Church
BB17092, Barbados

Authorised Representative Name /Location/SRN:
CMI spol s.r.o.
Trencianska 47
821 09 Bratislava
Slovakia
SK-AR-000007425

Notified Body Name & Number
BSI Group The Netherlands B.V. (2797)

CLASSIFICATION RATIONALE (EC):	ANNEX VIII, RULE 8 APPLIES
RISK CLASS:	IIb
COMMON SPECIFICATIONS:	None
PRODUCT TYPE:	HEMA Intraocular Lens
MODEL #:	Softec I

©Dec-Softec I

INTENDED PURPOSE:

The Lenstec Softec I posterior chamber intraocular lenses are ultraviolet absorbing 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. Patients meeting all of the following criteria should be considered suitable for implantation: · 18 years or older · Male or Female · Any race · Able to provide written informed consent. The lenses are indicated for primary implantation when a cataractous lens has been removed by phacoemulsification with circular tear capsulotomy and the posterior capsule intact.

SRN: BB-MF-000019262

Basic UDI-DI: 08443690SOFTECIWL

Certificate of Conformity declared in Barbados on the 15th July 2024 by

Ian Hickling
PRESIDENT
(Signed on behalf of Lenstec (Barbados) Inc.)

LENSTEC (BARBADOS) INC.

Digitally signed by AVETISYAN ARMEN 2325020185
Date: 2026.11.10 16:58:51 AMT

©Dec-Softec I