



LENSTEC (BARBADOS) INC.

Airport Commercial Centre • Pilgrim Road • Christ Church, BARBADOS BB17092
Telephone: (246) 420-6795 • Fax: (246) 420-6797 • E-mail: lenstecbarbados@lenstec.com

EC – 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 Council directive **93/42/EEC** as amended by **2007/47/EC** and has been subject to the conformity procedures laid down in **Annex II, Section 3.2** under the supervision of the British Standards Institution, a Notified Body authorized by the United Kingdom Competent Authority, and carrying the Notified Body Number 0086. Furthermore, we declare that we are certified ISO 13485 FM 38446 and have been allocated CE certificate CE01801 for the listed product.

Design Location

Lenstec Inc
1765 Commerce Ave. N
St. Petersburg, FL
33716, USA

Design/Manufacturing Location

Lenstec (Barbados) Inc
Airport Commercial Centre
Pilgrim Road, Christ Church
BB17092, Barbados

EC Representative Location

Lenstec (Barbados) Inc.
Lenstec House, Unit 8 Mariner Court
Calder Park
Wakefield, WF4 3FL
United Kingdom

Notified Body & Number

British Standards Institution (0086)

CLASS: IIb

PRODUCT TYPE: PMMA Intraocular Lens

MODEL #: LA-501

Certificate of Conformity declared in Barbados on the 2nd February 2012 by

Ian Hickling
PRESIDENT