



Certificate

Full Quality Assurance

No. CE 01764



Issued to:

**Labtician Ophthalmics Inc.
2140 Winston Park Drive
Unit 6
Oakville
Ontario
L6H 5V5
Canada**

In respect of:

The design and manufacture of sterile oculoplastic gold implants, sterile and bulk non-sterile silicone, silicone sponge and tantalum retinal implants, silicone oil extraction kits, silicone oil for ophthalmic implantation and ophthalmic surgical kits

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **13 Nov 1997**

Date: **20 Mar 2013**

Expiration Date: **7 Apr 2018**

Page: 1 of 1

Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

...making excellence a habit.™

Certificate

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor	Service(s) supplied
Sterigenics EO Canada, Inc. 781 Pharmacy Avenue Toronto Ontario Canada M1L 3K2	ETO Sterilization
Omega Laboratories Ltd. 11, 177 Rue Hamon Montreal Québec Canada H3M 3E4	Moist Heat Sterilization
MDSS GmbH Schiffgraben 41 30175 Hannover Germany	EU Representative

History of Quality Assurance Certificate

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Issue Date: 20 Mar 2013
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Date	Reference Number	Action
13 November 1997		First Issued
05 May 1999		Addition of oculoplastic implants to scope
02 May 2003		Addition of sterile silicone oil infusion sets and silicone oil for ophthalmic implantation and gold in oculoplastic implants and silicone, silicone sponge and tantalum non-sterile retinal implants to scope. Five Year Renewal
24 January 2008	7146352	Addition of new product 'silicone oil extraction kit' to scope
08 April 2008	7175703	Certificate Renewal
18 November 2010	7606113	Transfer of "sterile silicone oil infusion sets" from scope to CE 568889. Extension of scope to include "ophthalmic surgical kits" and the addition of 'MDSS GmbH' as EU Representative
20 March 2013	7961404	Certificate renewal. Change in name and address of significant subcontractor 'Sterigenics'