

chromogenex

Manufacturers Name: Chromogenex™

Manufacturers Address: Units 1 & 2 Heol Rhosyn
Parc Dafen
Llanelli
Carmarthenshire
SA14 8QG, UK.

Model Name: Chromolite EP™ Intense Pulsed Light System

Model Assembly Number: A00-1123

Serial Number: EPC027

Classification of Device
for 93/42/EEC: Class IIb

Description of Equipment: Intense Pulsed Light System designed for the removal of unwanted hair, treatment of moderate inflammatory acne vulgaris, benign pigmented epidermal lesions, cutaneous lesions, benign cutaneous vascular lesions.

Chromolite™ EP IPL System (A00-1123 – 240V 50Hz)	
Directives complied with:	Medical Devices Directive 93/42/EEC EMC Directive 2004/108/EC
Harmonised Standards to which conformity is declared:	IEC 60601-1:1988 + A1:1991 + A2:1995 BS EN 60601-1-2:2007

We the undersigned, hereby declare that the equipment specified above conforms to the above Directives and Standards and is subject to the procedure set out in Annex 2 of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS UK Ltd, 202b Worle Parkway, Weston-Super-Mare, Somerset, BS22 0WF

Signature: P.R. Bevan.

Date: 26-3-08

Position: Quality Manager

Full Name: Mr. Peter R Bevan *MinstP*

Location: Chromogenex

CE
0120



The management system of

Chromogenex Technologies Limited

Heol Rhosyn, Parc Dafen, Llanelli,
Carmarthenshire, SA14 8QG, UK

has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

**Design, manufacture, service and repair of Medical Laser Systems,
Intense Pulse Light Systems and Light and Vacuum Massage Devices.**

This certificate is valid from 21 November 2006 until 21 November 2009
Issue 8. Certified since 01 May 1998

Authorised by

P. Earl

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-2 0803

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DAVID BENNETT BCL
16 AXIS COURT
MALLARD WAY
SWANSEA VALE
SWANSEA
U.K.
SA7 0AJ
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