DGM

DANISH MEDICAL
DEVICES CERTIFICATION

EC Certificate

DGM-547

This is to certify that the quality system of

Ellipse A/S
Agern Allé 11
2970 Hørsholm
Denmark

has been approved in conformity with the requirements of

Annex II, section 3.2 - Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law.

The scope of the certification is:

Design, manufacture and testing of laser and incoherent light equipment for treatment of changes in the anatomy or of a physiological process in the skin, in class IIb

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of DS Certificering A/S. This EC certificate is issued pursuant to the DS Certificering A/S rules for the certification of medical devices and entitles the certificate holder to affix the CE mark.

Søren Bøgestrand
Authorized person

Valid from:	2009-06-10
Valid until:	2014-06-10
Initial date of issue:	2006-06-12
Reference:	Aur2a0903v220f105

DS Certificering A/S

Notified Body, Identification No. 0543
Kollegievej 6, DK-2920 Charlottenlund, Denmark

DS CERTIFICERING

DGM

DANISH MEDICAL
DEVICES CERTIFICATION

The following product families in class IIb are covered by the certificate:

Ellipse Flex serie
Ellipse Light serie
Ellipse Super Light serie
Ellipse Super Flex serie
Applicators
Dermatologic lasers
Laser scanners

Certificate number:	DGM-547	Valid from:	2009-06-10
Certificate type:	EC Certificate	Valid until:	2014-06-10
		Initial date of issue:	2006-06-12
		Reference:	Aur2a0903v220f105

DS
CERTIFICERING

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Product List

The following products are covered by DGM-547:

Product	Class	Date for placing on the market (with CE Mark)	Product family on DGM-547 covering the device
Ellipse Flex	IIb	Before 2005-09-30	Ellipse Flex serie
Masterlight Epil	IIb	Before 2005-09-30	Ellipse Flex serie
Photolyssis	IIb	Before 2005-09-30	Ellipse Flex serie
Ellipse Light	IIb	Before 2005-09-30	Ellipse Light serie
Epilux	IIb	Before 2005-09-30	Ellipse Light serie
Cosmolight	IIb	Before 2005-09-30	Ellipse Light serie
Ellipse Super Light	IIb	Before 2005-09-30	Ellipse Super Light serie
Ellipse Light SPT	IIb	Before 2005-09-30	Ellipse Super Light serie
Epilux II	IIb	Before 2005-09-30	Ellipse Super Light serie
Cosmolight Revolution	IIb	Before 2005-09-30	Ellipse Super Light serie
Ellipse I^2PL	IIb	2005-12-21	Ellipse Super Flex serie
Ellipse Super Flex	IIb	2005-10-10	Ellipse Super Flex serie
Ellipse Flex PPT	IIb	2005-10-10	Ellipse Super Flex serie
Ellipse Multiflex	IIb	2008-09-12	Ellipse Super Flex serie
Hair Applicator (HR), 9APP7133	IIb	2005-10-07	Applicators
Hair Applicator (HR-3), 9APP7578	IIb	2009-05-01	Applicators
Hair Applicator Small (HR-S), 9APP7116	IIb	2005-10-07	Applicators
Hair Applicator Dark (HR-D), 9APP7114	IIb	2005-10-07	Applicators

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www.dgm-nb.org

DS Certificering A/S
Notified Body No. 0543

DGM

Product	Class	Date for placing on the market (with CE Mark)	Product family on DGM-547 covering the device
Vascular Applicator (VL-2), 9APP7134	IIb	2005-10-07	Applicators
Pigment Applicator (PL), 9APP7212	IIb	2005-10-07	Applicators
Photo Rejuvenation Applicator (PR), 9APP7213	IIb	2005-10-07	Applicators
Pigment Applicator (PL-W), 9APP7377	IIb	2006-11-27	Applicators
Nd:YAG Applicator 9APP7472	IIb	2008-09-12	Applicators
Ellipse Juvia	IIb	2007-10-25	Dermatologic Lasers
9EJU7493	IIb	2008-10-02	Laser scanners

"The products on this list have been accepted by DGM"

Date: 2009-05-25

Name and signature: Carsten Worm Jensen

Title: Lead auditor

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DS Certificering A/S
Notified Body No. 0543

4.4 Conformidad CE

El Ellipse Flex PPT cumple con los requisitos de la Directiva 93/42/CEE del Consejo Europeo concerniente a los dispositivos sanitarios, y por tanto lleva el sello CE de Conformidad

Clasificación de Seguridad: El Ellipse Flex PPT tiene las siguientes clasificaciones:

Clase IIb según la Directiva 93/42/CEE sobre dispositivos médicos.

Clase I, Tipo B según la norma de seguridad EN 60601-1. Este equipo requiere una conexión de protección a tierra fiable.

NOTA EN REFERENCIA A LA APLICACIÓN DE REDUCCIÓN DE ARRUGAS: Esta aplicación cumple con los requisitos de la Directiva 73/23/EEC según lo acordado por 93/68/EEc relativa a equipos de bajo voltaje, debido a que la Directiva 93/42/EEC no cubre esta aplicación.

4.5 Símbolos CEI Utilizados

Indica Punto de Tierra de Protección

Corriente Alterna

| ENCENDIDO / Alimentación

o APAGADO / Alimentación

EQUIPAMIENTO TIPO B

Fabricante

Atención: antes de proceder, consulte las instrucciones detalladas en los documentos adjuntos.

No desechar este producto con la basura normal. Envíese a un centro de reciclaje autorizado

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DEVICES CERTIFICATION

Quality System Certificate

DGM-459

This is to certify that the quality system of

Ellipse A/S
Agern Allé 11
2970 Hørsholm
Denmark

fulfils the requirements in

DS/EN ISO 13485:2003 + AC:2007
and DS/EN ISO 9001:2008

The scope of the certificate is:

Development, design, production and service of IPL and Laser equipment for medical treatment

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of DS Certificering A/S.
The quality system certificate is issued pursuant to the DS Certificering A/S rules for the certification of quality systems for medical devices.

Søren Bøgestrand
Authorized person

Valid from:	2009-06-10
Valid until:	2012-06-10
Initial date of issue:	2006-06-12
Reference:	Aur2a0903v220f105

DS Certificering A/S

Notified Body, Identification No. 0543
Kollegievej 6, DK-2920 Charlottenlund, Denmark

DANAK

DS CERTIFICERING

QMI™
Management Systems Registration

Certificate of Registration

Issued to:

Danish Dermatologic Development A/S

Agern Allé 11, DK2970 Hørsholm, Denmark

CERT-0016058:	1051870
SIC Number / NACE Code:	3845 / DL33.1
Date of Original Registration:	June 21, 2006
Date of Current Registration:	June 21, 2006
Registration Expiry Date:	June 20, 2009

which has demonstrated that its Quality Management System is in compliance with:

ISO 13485:2003

under the Canadian Medical Devices Conformity Assessment System (CMDCAS)

The following scope of registration applies:

Design, manufacture, testing and service of Intense Pulsed Light systems and related accessories.

CMDCAS Recognized Registrar

QMI REGISTERED

Wendy J. Tilford
President