



Santé Health
Canada Canada

LN/NH: 61237

Therapeutic Products Directorate
Medical Devices Bureau
Direction des produits
thérapeutiques
Bureau des matériels médicaux

Medical Device Licence Homologation d'un instrument médical

Date of Issue/ Date de délivrance:

DEC 18 2002

Licence Number/No d'homologation:

61237

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with Medical Devices Regulations, Section 36, for the following medical device/La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Device Name/Nom de l'instrument:

HAIRMAX LASERCOMB

Issued to Manufacturer Name & Address/Délivrée au nom du fabricant & adresse

LEXINGTON INTERNATIONAL, LLC

4800 NORTH FEDERAL HWY.
SUITE 305A
BOCA RATON, FLORIDA
UNITED STATES
33431

Director, Medical Devices Bureau/Directeur des matériaux médicaux

Class II Devices/Instruments médicaux de classe II

Director General, Therapeutic Products Directorate/Directeur général, Direction des produits thérapeutiques

Class III & IV Devices/Instruments médicaux de classes III et IV



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Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

HAIRMAX LASERCOMB

Device ID/No de l'instrument: 415874

Model/Catalog Detail/No de modèle/Catalogue:

HAIRMAX LASERCOMB



APPLICATION FOR A NEW MEDICAL DEVICE LICENCE

(disponible en français)

11. PURPOSE/INTENDED USE:

A description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented; (Note: Failure to supply an appropriate level of detail may result in the application being rejected.)

Indications for use: 1) Strengthening of scalp hair in men and women.
 2) Prevention of scalp hair loss in men and women.
 3) Regrowth of scalp hair in men and women.

Patient population: General adult population of men and women.

Anatomical particular: To be used on the hair bearing scalp of men and women.

Energy Source: A 110 volt electric cord serves as the energy source for the medical device.

20(1)(b)

10/29/2003 12:29 FAX 813 946 6563

Renewal Section

001



Health
Canada

Santé
Canada

Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Medical Devices Bureau
Therapeutic Products Directorate
Room 1605
Statistics Canada Main Bldg.
Tunney's Pasture

Address Locator: 0301H1
OTTAWA, Ontario K1A 0L2

Date: 10/24/2003
File Number: 115979

DR. MARTIN UNGER
M.D. COSMETIC PRODUCTS LTD.
1401-484 AVENUE ROAD
TORONTO, ONTARIO
CANADA
M4V 2J4

Dear DR. MARTIN UNGER

Re: Medical Device Licence Renewal

This is in reference to your letter received on October 23, 2003 concerning the manufacturer listed below.

Manufacturer's Name LEXINGTON INTERNATIONAL, LLC Manufacturer ID: 116710

We can only accept a valid Quality System certificate from a registrar recognized by the Canadian Medical Device Conformity Assessment System (CMDACS). As soon as you obtain a valid certificate, please fax it to us at (613)946-6563 and confirm by mail. If we do not receive the certificate by November 1, 2003, the following procedure will apply:

The Medical Devices Bureau cannot delay the quality system requirements for November 1, 2003. The licence renewal process cannot be put on hold. Following November 1, a process will begin towards the cancellation of a licence. You will be notified by a warning letter as to when your device licence will be cancelled.

A cancelled licence can be reinstated within 6 months of cancellation by resubmitting an application, cross referencing the old licence. A \$200.00 fee would be required for Class 2 licences and Class 3 and 4 licences that have undergone a review under the new regulations.

If you require further information or have further questions concerning this matter, please contact us or consult our web site at www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dp/index_devices_quality_e.html.

Yours truly,

Don Boyer
Manager
Licencing Services Division

questions about quality system certificate:
ISO13485_CMDACS_SCECIM@HC-SC.GC.CA
questions about renewal:
licence_renewal@hc-sc.gc.ca Fax (613)946-6563
james_h_moore@hc-sc.gc.ca (613)954-0736
pasca_lariviere@hc-sc.gc.ca (613)946-6553

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pascale_lariviere@hc-sc.gc.ca (613)946-6553