

## **CERTIFICATE**OF REGISTRATION

This is to certify that the management system of:

## **Lexington International LLC**

(DUNS # 10-426-5165)

Main Site: 1040 Holland Drive

Boca Raton, Florida 33487, USA

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

**Brazil**: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

**United States**: 21 CFR 820 <u>OR</u> 21 CFR 820.180 and 198, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

The design and manufacturing of low level laser medical device used to promote hair growth.

**Certificate Number:** 

0079595-00

**Initial Certification Date:** 

2018-08-24

Certification Effective Date:

2018-08-24

**Certification Expiry Date:** 

2021-08-23



Calin Moldovean

President, Business Assurance

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