By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 689400**

Issued To: **Shenzhen LeafLife Technology Co., Ltd.**
4F, Bldg.C, JMD Industrial Park
No.39 Qingfeng Blvd., Baolong Industrial Area
Longgang Dist.
Shenzhen City
Guangdong
518116
China

In respect of:

The design, development, manufacture of laser therapy devices and non-laser light therapy devices for the treatment of hirsutism.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2020-02-19** Date: **2020-02-19** Expiry Date: **2024-05-26**

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Supplementary Information to CE 689400

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIb		
MD 1402	Laser therapy device	The Laser therapy device is intended for use in dermatologic and general surgical procedures for hair removal and permanent hair reduction. It is applicable to hirsutism caused by hormone therapy.
MD 1402	LED therapy device	The LED therapy device is intended for use in dermatologic and general surgical procedures for hair removal and permanent hair reduction. It is applicable to hirsutism caused by hormone therapy.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 689400**

Date: **2020-02-19**

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Date	Reference Number	Action
19 February 2020	8896292	First issue.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
20 October 2023	30026939	Change EU representative from "Luxus Lebenswelt GmbH" to "CMC Medical Devices & Drugs S.L."

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Inspiring trust for a more resilient world.

20 October 2023

Shenzhen LeafLife Technology Co., Ltd.
4F, Bldg.C, JMD Industrial Park
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Longgang Dist.
Shenzhen City
Guangdong
518116
China

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 689400	93/42/EEC Annex II excluding Section 4	30026939	Change EU representative from "Luxus Lebenswelt GmbH" to "CMC Medical Devices & Drugs S.L."

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices