



EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 702548

Issued To: Beijing Superlaser Technology Co., Ltd.

2nd Floor, Building 3, No.2 Zhongfu St. Xinjian Wulianhuan Development Zone

Xihongmen Town Daxing District

Beijing 100076 China

In respect of:

The manufacture of multi-modality skin surface treatment systems and photobiomodulation systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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

Gay C Stade

This certificate was issued electronically and is bound by the conditions of the contract.

First Issued: **2020-08-06** Date: **2020-08-06** Expiry Date: **2024-05-26**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.





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Supplementary Information to CE 702548

Issued To:

Beijing Superlaser Technology Co., Ltd. 2nd Floor, Building 3, No.2 Zhongfu St. Xinjian Wulianhuan Development Zone Xihongmen Town

Daxing District Beijing 100076 China

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1402	Multi-modality skin surface treatment systems	Not applicable for class IIa
MD 1402	Photobiomodulation systems	Not applicable for class IIa

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Page 2 of 2

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 702548**Date: **2020-08-06**

Issued To: Beijing Superlaser Technology Co., Ltd.

2nd Floor, Building 3, No.2 Zhongfu St. Xinjian Wulianhuan Development Zone

Xihongmen Town Daxing District

Beijing 100076 China

Subcontractor: Service(s) supplied

A. K. vigrous global trading ltd1 – Agias ElenisNicosiaCyprus

EU Representative

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 702548**Date: **2020-08-06**

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Xihongmen Town Daxing District

Beijing 100076 China

Date	Reference Number		Action
Current	9671050	First issue.	THE PERSON NAMED IN COLUMN TO PERSON NAMED I

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Page 1 of 1

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