By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 632901**

Issued To: **Deleo S.A.**
Pôle d'Excellence Jean-Louis
Fréjus
83600
France

In respect of:

Design and Manufacture of high-powered LED lamps for dermatologic purpose, of cryotherapy and cryolipolysis devices for diminishing localized subareolar fat for male patients with pseudogynecomastia, of non-ablative fractional lasers for the treatment of acne, scarring and melasma, of non-ablative, non-fractional laser for treatment of hirsutism, and of non-invasive electromagnetic stimulation device for the treatment of urinary incontinence.

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: **2015-07-03** Date: **2021-04-29** Expiry Date: **2024-05-26**

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
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Supplementary Information to CE 632901

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Device code	Device name	Intended purpose per IFU
Class IIb		
MD 1402	Laser Origin - Laser device for dermatologic purpose	Treatment of inflammatory acne Treatment of Melasma Attenuation of scars
	SUBLIM - Laser device for dermatologic purpose	Treatment of hirsutism
Class IIa		
MD 1402	Medisol – LED lamp using non ionising radiation	Acne treatment Treatment against pigmentary disorder
MD 1402	Cristal and Cristal PRO - Cryotherapy, cryolipolysis devices	Non-invasive cryolipolyse for diminishing localized subareolar fat for male patients with pseudogynecomastia
MD 1103	Cristal FIT - Electromagnetic pulsed stimulator	Rehabilitation of weak pelvic muscles for the treatment of urinary incontinence (UI) in men and women.

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EC Certificate - Full Quality Assurance System Certificate History

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Date: **2021-04-29**
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Date	Reference Number	Action
03 July 2015	8297106	Initial Issue. Transfer from another Notified Body.
23 Sept 2015	8417923	Extension of the scope from "Design and Manufacture of high powered LED lamps for dermatologic purpose" to "Design and Manufacture of high powered LED lamps for dermatologic purpose and, cryotherapy and cryolipolysis devices for pain relief and treatment of localised fat in people who are overweight".
31 March 2016	8500892	Change of company address from '51 Impasse Thomas Edison, ZA La Palud, Frejus 83600, France' to 300, Rue Isaac Newton, Technoparc Epsilon 1, Saint Raphael 83700, France'.
19 June 2016	8500589	Certificate renewal.
20 February 2019	8855866	Traceable to NB 0086.
02 April 2019	9684855	Extension to scope to include "non-ablative lasers for the treatment of acne, scarring and melasma". Addition of supplementary device table and removal of "Medelisol" device from the device table.
21 November 2019	3078289	Extension to scope to add 'non-ablative, non-fractional laser for treatment hirsutism'.

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Date	Reference Number	Action
Current	3427457	Certificate renewal. Extension to scope to include "Electromagnetic stimulation device…" Correction of intended use for cryotherapy and cryolipolysis devices. Manufacturer address change. Device table update with precision of certified medical indications for devices of class IIa.

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