

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.S.**
300, Rue Isaac Newton
Technoparc Epsilon 1
Saint Raphael
83700
France

In respect of:

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.

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **03 July 2015**

Date: **31 March 2016**

Expiry Date: **16 August 2016**

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Page 1 of 1

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 632901**
 Date: **31 March 2016**
 Issued To: **Deleo S.A.S.**
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Technoparc Epsilon 1
Saint Raphael
83700
France

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'

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Page 1 of 1

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