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By Royal Charter

EC Certificate - Full Quality Assurance System

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

No.

CE 700456

Issued To:

Wuhan Dimed Laser Technology Co., Ltd.
Room 311,313,315, Building 1
Great Wall Innovative Science Park
Tangxunhu North Road
East Lake Development
Wuhan
Hubei
430000
China

In respect of:

The Design, Development and Manufacture of Medical Diode Laser Systems

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: **2020-11-13**

Date: **2020-11-13**

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

Information and Contact: BSI, 389 Chiswick Park Avenue, Uxbridge, Middlesex, UK. Tel: +44 (0)1895 531100
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 700456**
 Date: **2020-11-13**
 Issued To: **Wuhan Dimed Laser Technology Co., Ltd.**
Room 311,313,315, Building 1
Great Wall Innovative Science Park
Tangxunhu North Road
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Wuhan
Hubei
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Date	Reference Number	Action
Current	9655216	First issue. Transfer from another Notified Body.

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Page 1 of 1

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List of Significant Subcontractors

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

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Tangxunhu North Road
East Lake Development
Wuhan
Hubei
430000
China

Subcontractor:

Luxus Lebenswelt GmbH
Kochstr. 1
Willich
47877
Germany

Service(s) supplied

EU Representative

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Supplementary Information to CE 700456

Issued To:

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NBOG Code	Device Name	Intended purpose per IFU
Class IIb		
MD1104	Medical Diode Laser Systems	BERYLAS is used to cut, excise, vaporize, and coagulate tissues in various dental applications such as oral soft-tissue surgery, gingivectomy, and diminish inflammation.

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Page 2 of 2

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