



# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.: 1000364969-PA-NA-KOR Rev.1.0

Project No.: PRJC-590864-2018-MSL-KOR

Valid Until: 27 May 2024

This is to certify that the quality system of:

### **ILOODA Co., Ltd.**

120, Jangan-ro 458beon-gil, Jangan-gu, Suwon-si, Gyeonggi-do, 16200 Korea

For design, production and final product inspection/testing of:

**Diode, CO2, Q-Switched Nd:YAG, Nd:YAG and Alexandrite laser system, High frequency surgical system with sterile micro needle electrodes, and Laser applicator with sterile beam guide, High intensity focused Ultrasound system**

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:  
Høvik, 21 April 2021

For the issuing office:  
Notified Body 2460  
DNV Product Assurance AS



*Eugenie Winger Husebye*  
Eugenie Winger Husebye  
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

ICP-4-5-11-MDD-f2, rev.0

## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

### Certificate history:

Revision	Description	Issue Date
0.0	Original certificate No. 285643-2019-CE-KOR-NA-PS. New models added	06 May 2020
<b>1.0</b>	<b>Scope extension to new model (AcuTron)</b>	<b>21 April 2021</b>

### Products covered by this Certificate:

Product Description	Product Name	Class
Diode laser system	VIKINI(DET-C1), VIKINI <sup>PLUS</sup> (DET-C2), EPILIA RF(ERF-C1), VeLux 755(DEL-C1), Healer 1064(DOL-C1)	IIb
Diode laser system	Lumilas(DAL-C1)	IIb
Q-Switched Nd:YAG laser system	CuRAS(QND-C1)	IIb
CO2 laser system	FRAXIS(FRX-C1)	IIb
CO2 laser system and High frequency surgical system with sterile micro needle electrodes	FRAXIS DUO(FRX-C2)	IIb
High frequency surgical system with sterile micro needle electrodes	SECRET RF(MTR-C1), Sterile micro needle electrodes: MTR-AC-10, MTR-AC-C-10, MTR-AC-16, MTR-AC-C-16, MTR-AC-25, MTR-AC-C-25, MTR-AC-64, MTR-AC-C-64, MTR-AC-19G, MTR-AC-22G, MTR-AC-27G, MTR-AC-04, MTR-AC-01, MTR-AC-25s, MTR-AC-C-25s	IIb
<b>High frequency surgical system with sterile micro needle electrodes</b>	<b>AcuTron</b>	<b>IIb</b>
Laser applicator and sterile beam guide	Gynolaser and i-slide	IIb
Diode laser system and High frequency surgical system with sterile micro needle electrodes	Secret DUO	IIb
Nd:YAG laser system and Alexandrite laser system	PENTO 9900	IIb
High intensity focused Ultrasound system	hyzer me	IIb



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The complete list of devices is filed with the Notified Body

**Sites covered by this certificate**

Site Name	Address
ILOODA Co., Ltd.	120, Jangan-ro 458beon-gil, Jangan-gu, Suwon-si, Gyeonggi-do, 16200 Korea

**EU Representative**

Obelis s.a, Bd. General Wahis 53 1030 Brussels, BELGIUM



## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate