Manufacture's Declaration of Laser Radiation of Safe Laser devices

Company: **Laser Light Medical Innovation Ltd.**

Address: **Hungary, 1138 Budapest, Hajóépítő sétány 4. B.IX.201.**

as manufacturer we declare that our products

Name : **Therapeutic Laser Devices**
- **Safe Laser 1800 Infra,**
- **Safe Laser 500 Infra,**
- **Safe Laser 150,**

are Medical Devices suitable for professional and for personal use.

They radiate a special scattered laser light which is safe for human eyes according to the standard: Safety of laser products - Part 1: Equipment classification and requirements (IEC 60825-1:2014)

Laser safety: Class I.

Some countries have import restrictions on hand held, battery operated, laser pointers with an assessable emission level greater than 1mW which emits dangerous parallel laser beam.

The Safe Laser Medical Devices are NOT “laser pointers”.

Hungary, Budapest, 11 July 2025

Tamas Rozsa

CEO Safe Laser

For more information contact:
info@safelaser.eu

certiso

144783-18-09-05

EC CERTIFICATE

Full Quality Assurance System
Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Kft. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Laser Light Orvostechnikai Innovációs Kft.

Headquarters: 1139 Budapest, Kartács utca 8. 4. em. 4., HUNGARY

Scope:

Therapeutic laser equipment

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
soft laser	Safe Laser 150	laser light therapy	SL150	II.a
soft laser	Safe Laser 500 Infra	laser light therapy	SL500	II.a
soft laser	Safe Laser 1800 Infra	laser light therapy	SL1800	II.a

This certificate is valid in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 56-CE-180618

Issue: 3
Issued: 14 May 2021
First issued: 05 September 2018
Start date of certified status: 05 September 2018

Expires:
04 September 2023

CE Certiso Kft.
H-2092 Budakeszi, Erdő u. 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

CE Certiso
Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 25147049-2-13

Valter PAPP, Dr.
General Manager

CE Certiso Ltd. NB2409 Notified Body

CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. – NB 2409
H-2092 Budakeszi, Erdő utca 101.

15 December 2023

Notified Body Confirmation Letter

Reference: K-2023/161

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2409 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Laser Light Orvostechnikai Innovációs Kft.
Hajóépítő sétány 4.B. IX. 201.
1138 Budapest
HUNGARY

SRN Number (if available): HU-MF-000017714

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided

evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Valter PAPP, dr.

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Safe Laser 150 – soft laser **5999573960024LA**	Class IIa	N/A	Certificate 144783-18-09-05; NB 2409
Safe Laser 500 Infra – soft laser **5999573960017LD**	Class IIa	N/A	Certificate 144783-18-09-05; NB 2409
Safe Laser 1800 Infra – soft laser **5999573960000KU**	Class IIa	N/A	Certificate 144783-18-09-05; NB 2409

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NB ID number: 2409

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
15-12-2023	K-2023/161	Initial issue

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NB ID number: 2409