

Manufacturer's Declaration of Laser Radiation of Safe Laser devices

Company: **Safe Laser Bt.**

Address: **Hungary, 1139 Budapest, Kartács utca 8. 4/4.**

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)

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 2018



Tamas Rozsa

CEO Safe Laser

For more information contact:
info@safelaser.eu



144783-18-09-05
EC CERTIFICATE

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

CE Certiso Ltd. (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:
Safe Laser Bt.

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	IIa
soft laser	Safe Laser 500 Infra	laser light therapy	SL500	IIa
soft laser	Safe Laser 1800 Infra	laser light therapy	SL1800	IIa

This certificate is valid in case of successfully conducted annual surveillance audits.
ID number of the related audit report: 56-CE-180618

Issue: 1
Issued: 05 September 2018
First issued: 05 September 2018
Start date of certified status: 05 September 2018
Expires: **04 September 2023**

Valter PAPP, Dr.
General Manager



CE Certiso Ltd.
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