

# Manufacturer's Declaration of Laser Radiation of Safe Laser devices

Company: **Safe Laser Bt.**

Address: **Hungary, 2011 Budakalász, Fecske u. 7.**

as manufacturer we declare that our products

Name : **Therapeutic Laser Devices**

**Safe Laser® 500 Infra, Safe Laser® 150, Safe Laser® 30**

are Medical Devices 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 60825-1:2007)

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".

This declaration is valid for personal use and NOT for commercial laser import.

Hungary, Budakalász, 31 July 2014

  
Tamas Rozsa  
CEO Safe Laser

For more information contact:  
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**Safe Laser®**



144446-13-08-16

EC CERTIFICATE

**Production Quality Assurance**  
Directive 93/42/EEC on Medical devices, Annex V

CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering (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: **2011 Budakalász, Fecske u. 7. HUNGARY**

Scope:

**Therapeutic laser equipment**

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class	Start date of certified status
therapeutic low-intensity laser	Safe Laser	laser light therapy	SL30	II.a	16 August 2013
soft laser	Safe Laser 150	laser light therapy	SL150	II.a	04 April 2014
soft laser	Safe Laser 500 Infra	laser light therapy	SL500	II.a	31 July 2014

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

ID number of the related audit report: 56-CE-130704

Issue: 3  
Issued: 31 July 2014  
First issued: 16 August 2013

Expires:  
**15 August 2018**



CE Certiso  
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NB ID number: 2409

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