

SAF LASER®

Medical Soft Laser devices

Ear complaints

- inflammation, pain, varicose vein
- tinnitus

Allergy, Asthma, Hay fever, Respiratory inflammation

- eliminates or heals symptoms

Dental problems

- toothache, inflammation
- atrophy and bleeding gums
- oral mucosal injury

Musculoskeletal symptoms

- Meniscus lesion-
- ligament and joint capsule injury,
- joint swelling,
- pain and inflammation,
- rheumatic pain and inflammation,
- hematoma,
- post-operative swelling and arthritis,
- bone fractures....

Cosmetics

- akne, pimple
- crease, pigment spots...

Sports injuries

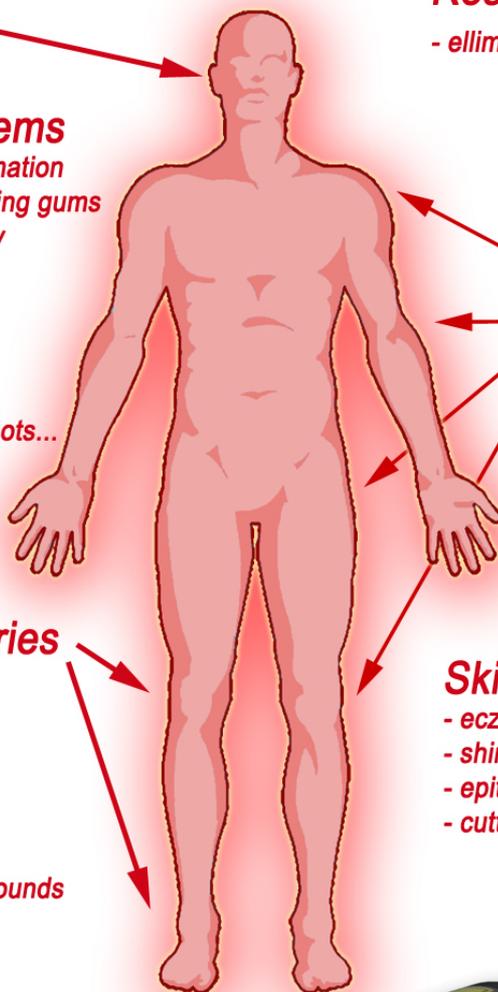
- muscle strain
- contusion
- hematoma

Skin problems

- eczema, dermatitis
- shingles, herpes
- epithelial injury, bruises
- cuts, flash burn, frostbite injury...

Diabetes

- heals ulcerated wounds



“Hungarian medical novelty with 50 years of professional background”



Introduction

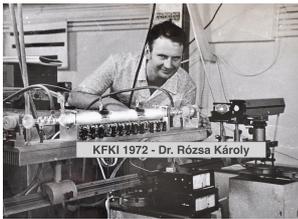
The Safe Laser company is a professional manufacturer of medical soft-laser devices. The three founders: Károly Rózsa (laser physicist, doctor of Hungarian Academy of Sciences), Mónika Peics (teacher) and Tamás Rózsa (electrical engineer).

Safe Laser Bt. is responsible for **developing and producing medical lasers.**



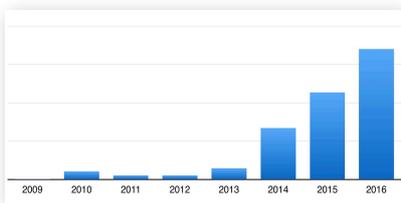
The Safe Laser Trade Ltd. performs educational, **commercial, marketing activities** and doing all related researches.

According to decree of Ministry of Health 4/2009 (III.17) our soft laser devices belong to class II.a. division of medical equipment.



Our company's co owner **DR. Károly Rózsa (DSc)** deals with **laser research and development since 1963.** He owns a number of patents on gas lasers construct. His name is associated to the **first successful polar light healing treatment**, which led to the subsequent patent of medical and cosmetic lamps radiating polarized light.

The **"Safe Laser Light" technology**, developed in 2012, has opened up a new chapter in the history of lasers. It made it possible for **high-power lasers to be safely used without danger to eyes.** (according IEC 60825-1:2014) This significantly expanded the range of laser users, because these devices can be used not only in hospitals and institutions, but also people **can safely operate it even at home**, every day.



Last 3 years we **sold more than 5 000 laser devices.** Our current production capacity is 1 000 pcs monthly and can be increased to 10 000 pcs with our current technology.

During development of lasers we are working closely with prominent professionals from different medical fields (hospitals, physician training centers) and jointly creating tools, which are effective, safe and comply with the highest standards.



Our company has a quality management system specified in MSZ EN ISO 13485: 2012 standard and production quality assurance according Directive 93/42/EEC on Medical devices, Annex V.



144446-13-08-16

EC CERTIFICATE

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

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:

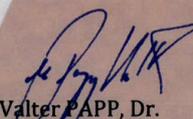
| Description of the device | Type | Intended use | Model | Risk class | Start date of certified status |
|---------------------------------|----------------------|---------------------|-------|------------|--------------------------------|
| therapeutic low-intensity laser | Safe Laser | laser light 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: 4
Issued: 29 January 2018
First issued: 16 August 2013

Expires:
15 August 2018


Valter PAPP, Dr.
General Manager



References

- State Medical Centre - Central Hospital of the Hungarian Homeland Defense Forces - physiotherapy, rehabilitation - Budapest, Hévíz
- Sándor Péterffy Street Hospital, Clinic and Trauma Center - Emergency Rehabilitation Department
- Hospitaller Order's Hospital - Buda - Orthopedics Department
- MRE Bethesda Children's Hospital - Rehabilitation Outpatient Clinic
- St. John Hospital and North Buda Unified Hospitals - traumatology
- ORFI (National Institute of Rheumatology and Physiotherapy) Department of Radiology
- Uzsoki Hospital - Central intensive care unit
- Semmelweis University, Faculty of Dental Sciences, Clinical Periodontology
- Semmelweis University, Department of Ophthalmology
- Unified St. István and St. László Hospital and Clinic - Department of Surgery
- BLESZ, Downtown - Lipót-town Health Service - Ear, nose and throat department
- Odon Jávorszky City Hospital (Hospital Vac) - Ear, nose and throat department
- Central Medical unit of Police – Budapest
- Hungarian Swimming Association
- Hungarian Association of Coaches



About lasers in general

The lasers in medicine in terms of biological activity can be divided into two categories:

- **High power = "hard lasers" - surgical lasers**
- **Low power = "soft lasers" - therapeutic lasers**



The **Safe Laser®** devices belong to therapeutic "**soft lasers**" group.

In case of soft lasers, the laser light uses the effect of photochemical reaction to start the beneficial biological processes. (photobiomodulation)

How does the soft laser therapy work?

Research in 1947 has already shown that mitochondria in the cells of our body are light sensitive. Mitochondria in various cells react differently to different wavelengths of the light. In the light spectrum the most powerful healing effect have red (eg. 660 nm) and infrared (eg. 808nm) lights.

The molecules in the energy absorption foto acceptor (light-absorbing) cells get activated by the soft laser and can activate another molecules, thereby initiate chemical reactions in the surrounding cells, tissues.

What are the physiological effects of the soft-laser light?

The soft-laser treatment has three known healing effects on the human body:

1. **Biostimulating effect - stimulates the body's own healing ability!**
2. **Reducing inflammation**
3. **Pain relief**



Safe Laser® devices are divided into two major groups:

1. **Red (660 nm) laser light: Safe Laser® 150**
2. **Infrared (808 nm) laser light: Safe Laser® 500 Infra**

Which laser is used for which illness?

The red (660nm) lasers mainly have **effect on the skin** to a depth of 3 cm, therefore they have a significant role in curing surface lesions, inflammation and pain and are suitable for treating illnesses by lightening the nasal mucosa (e.g. allergies, rhinitis ...)



The infrared (808nm) laser light can also be used in **much deeper** layers (it can apply a biological effect in 8 cm depth), so it can be excellently used for example **musculoskeletal disorders therapy**, in which it has analgesic, anti-inflammatory effects and accelerates the healing of muscles, tendons and joint.

At higher doses it is suitable for articular cartilage and cartilage regeneration as well.

Safe Laser application

Medical / health care:

- Family Medicine
- Dermatology
- Sports medicine
- Rheumatology
- Orthopedics, traumatology
- Dentistry
- Ear, nose and throat, allergy
- Diabetology
- Maternal and Child Health Nurse
- Home-care system
- Rehabilitation

Non medical:

- Retirement home
- Foundations
- Nursing homes
- Family Support Sites
- Nurseries
- Kindergartens
- Schools

Safe Laser experiences in the State Medical Centre - Central Hospital of the Hungarian Homeland Defense Forces



In our institution we use Safe Laser devices for 2 years, during which time a comprehensive study was carried out involving hundreds of patients examining the effectiveness of the therapy. During the treatments we have achieved outcomes for the following complaints and disorders:

Musculoskeletal disorders

- arthritis – chronic inflammation of the joints (fingers, wrist, elbow, ankle, knee, shoulder)
- rheumatoid arthritis – rheumatoid arthritis, pains
- arthrosis – eroded joints (especially hip, knee, shoulder)
- spondylarthrosis, lumboischialgia, discus hernia – (neck, back lumbar section)
- tenosynovitis – inflammation of the tendon sheath (wrist, Achilles tendon)
- epicondylitis humeri lateralis et medialis – tennis and golf elbow
- Carpal- tunnel syndrome
- de Quervain-syndrome
- tendinitis – inflammation tape (knee, shoulder)
- exostosis calcanei – spurs
- haematoma – in muscles, joints
- contusion, distorsion – sprains, bruises, strains (muscles, joints, ligaments)

Opinions:

In case of the treatment of acute and chronic musculoskeletal complaints, the pain of the treated person has been improved to such an extent that the rate of medication can be reduced, even omitted. The rehabilitation and healing expertise significantly has shortened.

A summary of the survey results

The use of Safe Laser is simple, qualifications, safety measures are not required, but it is necessary to carry out an instruction course and to comply with the indication and contraindication.

In case of acute illness usually 1-3 treatments are sufficient to achieve a positive outcome, so the process does not go through a long and costly chronic condition to be treated.

Patients bear the treatment well, because they feel no particular side effect, which is especially important for children.

Treatment duration is short, usually 5-20 minutes.

It is a good supplement to any other physical therapy and it can be given to mono- and combination treatment. Effective for pain, shortens the healing time.

It reduces the need for drugs, so these possible side effects are reduced too.

A handwritten signature in blue ink is written over a circular blue stamp. The stamp contains the text '32-964', 'Dr. Sandra', and '04103'.

Budapest, 22.05.2015.

Prof. Dr. Sandra Sándor med.habil. Ph.D.

dr. Gergely Kiss three-time Olympic champion water polo player, legal expert in sports law

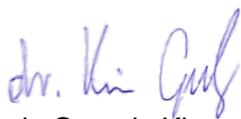
In thirty years of my career, I have done tens of thousands trainings and thousands of matches, I took part in four Olympic Games and seven world championships.

I could not avoid some damages during the amazing amount of work, which are the typical wear and tear of the cartilage indicating its detachments, both in knees and shoulders. On a daily basis we pursue with minor inflammation and strains in the world of professional sports.

There are several healing methods and excellent specialists, who help our career, but a recently thoroughly tested tool, Safe Laser 500 Infrared, has brought me the most noticeable improvement in terms of my shoulder problems.

It was easy to use and after 20-25 times the pain, which inhibited my movement was gone, in spite of my daily exposure. I was able to train without complaint in the gym, water, and I didn't have problems at the Racionet Military first class league matches. The stabbing pain sensation, which caused bitterness in my everyday life and reduced my movement scope thus belongs to the past, I optimistically look forward to my 24th first class season in terms of my health.

I am sure that for every water polo team, which has encountered barriers to effective work and has experienced acute and chronic knee, back, elbow and shoulder injuries, Safe Laser device is an effective solution.



dr. Gergely Kiss

Budapest, 26.05.2015.



Safe Laser experiences - Hungarian Olympic swimming team

Attila Györki
Masseur
Hungarian Olympic swimming team



As a massage therapist I mostly deal with athletes and top athletes. Understandably it is particularly important for their performance to be the best possible at trainings and at competitions too. To achieve good performance, painless freedom of movement is required.

There is no such athlete, who can avoid smaller or bigger injuries during their career. In this case, rapid assistance and effective rehabilitation is crucial.

Mostly I work next to the Hungarian Swimming Team. As a masseur I experienced how much load makes use of the swimmer's body. During the swimming and fitness training sessions, pain often occurs in the spine, knees, hips and shoulder, because of the pain arising from muscle fatigue due to high stress.

The Safe Laser is recommended by Dr. György Hegedűs, and he lent it to me for the duration of training camp last year, before the Doha Short Course Swimming World Championships. As fate would have it, next to chronic shoulder, knee and hip problems, I used the laser in connection with an acute injury suffered during a conditioning workout.

The technology has proved effective in each area, while the change was most striking for acute neck problem: a few weeks before the World Cup the athlete ultimately did not have to miss out a workout. I believe that without the laser, the swimmer wouldn't be able to carry out a complete training session, not to say, that would have left quite a mark on his world championship appearance.

After the experience with Safe Laser and what I have read about the device, I look forward to continue my work with the assistance of the laser technology. I believe that the Safe Laser has a place in sports rehabilitation.

A handwritten signature in blue ink that reads "Györki Attila".

Attila Györki

Safe Laser - Clinical research

Our company's mission is to research the fields of laser applications and expand the existing range of indications.

Annually we value over a thousand case studies according to "Post Market Surveillance - PMS" then plan the clinical researches and the development of new laser devices.



Ongoing researches

- Hearing loss
- Tinnitus
- Reducing the time for orthodontics
- Corneal ulcer
- Special optical arrangement for an eye safe 1500mW+ infrared laser

Future research areas (encouraging case studies):

- Stroke rehabilitation
- Diabetes treatment
- Alzheimer's Prevention and Treatment
- Myocardial infarction rehabilitation

Ocular Disorders

- Macular Degeneration (AMD)
- Corneal Ulceration
- Glaucoma (Glaucoma)
- Amblyopia (amblyopia)
- Old-age farsightedness

A handwritten signature in blue ink, appearing to read "Rozsa Karoly".

Dr. Karoly Rozsa

Head of Research and Development

A handwritten signature in blue ink, appearing to read "Rozsa Tamas".

Tamas Rozsa

Managing Director

Annexes:

- EMC_report_SL500_infra.pdf
- IEC60601_Safety_Performance_SL500_infra.pdf
- AD19_Certificate_Safe Laser_144446-13-08-16_B01580_en.pdf
- Declaration_of_conformity_all_devices.pdf
- Classification_SL500_English.pdf
- CE_Certiso_Notification.pdf