



Factsheets

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Cosmetic treatments using non-ionising radiation and sound

Background

Cosmetic treatments using non-ionising radiation (NIR) or sound, and the equipment used for this purpose are subject to new legal regulations.

- The Federal Act on Protection against the Risks associated with Non-ionising Radiation and with Sound (NIRSA) and the Ordinance to the Federal Act on Protection against the Risks associated with Non-ionising Radiation and with Sound (O-NIRSA) have governed the use of devices for cosmetic treatments since 1 June 2019. This factsheet describes the effect of these new regulations on treatments and providers of cosmetic services, whether commercial beauty salons, vocational beauty colleges or physicians.
- The new Medical Devices Ordinance of 1 July 2020, which governs the requirements of medical devices, is not covered in this factsheet.

1 Introduction

Cosmetic treatments using devices that produce non-ionising radiation (NIR) or sound can place substantial burdens on the skin, eyes and other tissue, and cause the health and safety limits to be exceeded. In order to ensure that client health is not endangered, the treatments listed under point 2.1.1 may only be performed by persons with a certificate of competence. These persons must complete training and pass examinations in order to obtain certificates of competence, which are mandatory from 1 June 2024. From this date, the cantonal enforcement authorities will check whether persons who perform these cosmetic treatments hold certificates of competence. However, cosmetic treatments using NIR and sound that require a medical history to be taken, must be performed under medical supervision. This also applies to NIR and sound devices which require medical knowledge to be used safely. Finally, certain treatments using NIR are prohibited on account of the dangers they pose.

Non-ionising radiation is defined by the Ordinance on Protection against the Risks associated with Non-ionising Radiation and with Sound (O-NIRSA) as electromagnetic fields with wavelengths greater than 100 nanometres.

It includes the following radiation spectra; listed are also the cosmetic treatments for which they are commonly used:

ultraviolet radiation, e.g. UV treatments; radiation from plasma devices;

- visible light, e.g. Intense Pulsed Light (IPL) flash bulbs, light-emitting diodes (LEDs), laser radiation, radiation from plasma devices;
- infrared radiation, e.g. infrared lamps, infrared LEDs; lasers with wavelengths over 780 nm, heating devices;
- high-frequency electromagnetic radiation, e.g. radio-frequency devices used to create fields or currents;
- low-frequency electromagnetic fields, e.g. low-frequency devices used to create fields or currents;
- galvanic currents;
- cold treatments.

Sound includes audible sound, infrasound, shockwaves and ultrasound of any wavelength.

2 Treatments with certificate of competence

2.1.1 Certificates of competence

From 1 June 2024, holders of a certificate of competence can perform the following treatments independently and without medical supervision.

Please note:

Doctors and practice staff instructed directly by them will also be permitted to carry out these treatments after 1 June 2024 without a certificate of competence.

People without a certificate of competence will no longer be permitted to carry out these treatments after 1 June 2024. This also applies to those who are attending training for the certificate of competence but have not yet passed the examinations and to those who have registered for the training for a certificate of competence.

For treatments with a certificate of competence, it is important to distinguish between the use of devices and the placing on the market of devices that are suitable for cosmetic treatments:

1. The O-NIRSA regulates the treatments and thus the use of NIR or sound devices on clients. It includes the use of all NIR and sound devices
 - to which a certificate of competence refers;
 - that are suited to these treatments according to the state of the art in science and technology and/or the training programme for the certificate of competence;
 - that are advertised for the treatments via the instruction manual, the product information or by other means;
 - that are used for this purpose by persons with a certificate of competence
2. However, the O-NIRSA does not regulate the placing on the market or the making available on the market of NIR or sound devices that are suitable for the individual treatments, nor does it set out requirements for such devices.

Tabelle 1 Certificates of competence

Certificate of competence (CC)	Associated treatments
CC laser acupuncture	Laser acupuncture
CC laser hair removal	Laser hair removal
CC hair removal using intense pulsed light (IPL)	Hair removal using intense pulsed light (IPL)
CC permanent make-up and tattoo removal	Laser removal of permanent make-up and tattoos that are not close to the eyes
CC skin and pigmentation	<p>Treatment of acne, wrinkles, scars, post-inflammatory hyperpigmentation and stretch marks</p> <p>Treatment of couperose, haemangiomas and spider naevi measuring less than or equal to 3 mm that are not close to the eyes</p> <p>Please note: Scars are not the same as wounds. The treatment of wounds using non-ionising radiation or sound may not be performed by persons with a certificate of competence and must be carried out under medical supervision</p>
CC cellulite and subcutaneous fat	Treatment of cellulite and subcutaneous fat
CC fungal nail infections	Treatment of fungal nail infections

2.1.2 Obtaining the certificate of competence from examining bodies

Certificates of competence may only be obtained from the examining bodies listed in the Annex to the 'FDHA Ordinance of 24 March 2021 on certificates of competence for treatments for cosmetic purposes using non-ionising radiation and sound' (in [German](#), [French](#) or [Italian](#) only). The training programmes for the certificates of competence equip candidates with knowledge of the fundamentals, the technologies used and treatment specific knowledge and skills, and comprise two compulsory practical treatments. They take around two weeks to complete and end with a compulsory examination. The training programme and examination must be completed with the same examining body. Training programmes for certificates of competence that are offered by course providers not listed in the Ordinance are illegal and invalid.

Process for obtaining certificates of competence for persons who already hold a certificate of competence

Persons who already hold a certificate of competence do not have to repeat the training on fundamentals and technologies. They do, however, have to complete the treatment specific training and examination and carry out the two practical treatments.

2.1.3 Shorter training to obtain certificates of competence

People with prior training

Beauticians with a Federal Diploma of Vocational Education and Training or an (Advanced) Federal

Diploma of Higher Education, dermapigmentologists with a higher education qualification, podiatrists with a Federal Diploma of Vocational Education and Training or an Advanced Federal Diploma of Higher Education, and TCM acupuncturists can complete a shorter training programme to obtain a certificate of competence. It takes around one week and ends with a compulsory examination. This option is not open to holders of any other vocational qualifications or those without a vocational qualification.

Recognition of previously completed laser protection courses

Certain examining bodies recognise previously completed laser protection courses, which means that the persons concerned can take advantage of a shorter training programme on technologies. Information on this is available from the examining bodies.

Recognition of longstanding professional practice:

Certain examining bodies waive the two compulsory treatments if the candidate can provide evidence of sufficient professional experience through client files and years of professional practice. Information on this is available from the examining bodies.

Recognition of other training programmes and certificates of competence for cosmetic treatments using NIR and sound

- Switzerland: Besides completed physician training, there are no other equivalent training programmes that are recognised as certificates of competence.

- Other countries: Applications for recognition of the equivalence of non-Swiss training qualifications may be submitted to the FOPH (anerkennungen-nissg@bag.admin.ch).
- All other courses, such as introductions to specific devices or treatment methods and continuing education programmes, are not recognised.

3 Treatments under medical supervision

The following **treatments** require a medical history and may only be performed by physicians or practice personnel directly instructed by them:

- actinic and seborrhoeic keratosis
- age spots
- angiomas/haemangiomas (greater than 3 mm)
- dermatitis
- eczema
- genital warts
- fibromas
- port-wine stains
- keloids
- melasma
- psoriasis
- syringomas
- sebaceous gland hyperplasia
- varicose and spider veins
- vitiligo
- warts
- xanthelasma

What is meant by *practice personnel directly instructed by them*?

Directly instructed practice personnel refers to persons who are employed by a physician and who work under their direct instruction, supervision and responsibility. This means that the physician is present during the treatment. Third parties who e.g. rent premises in a medical practice but practise their own activity there, or are assigned treatments by the practice, are not deemed practice personnel.

Treatments on the eyelids or under 10 mm from the eyes may only be performed by physicians and practice personnel directly instructed by them:

- Removal of permanent make-up
- Removal of tattoos and telangiectasia (couperose)
- Treatment of spider naevi and haemangiomas.

The following techniques can only be performed by physicians and practice personnel directly instructed by them:

- Treatments using high-intensity focused ultrasound (i.e. with ultrasound equipment whose maximum

effective intensity, maximum negative sound pressure and maximum beam non-uniformity ratio exceeds the limits of the IEC 60335-2-115: 2021 standard)

- Ablative laser treatments
- Treatments using long-pulsed Nd:YAG lasers (with pulse duration in the millisecond range).
- Photodynamic therapies combined with the application of phototoxic substances or drugs
- Laser lipolysis

Please note the following points that repeatedly require explanation

- Long-pulsed diode lasers with the same or similar properties to long-pulsed Nd:YAG lasers do not fall under the currently applicable regulations, although they exhibit the same hazard potential. Such products produce laser radiation with pulse durations in the millisecond range for wavelengths of around 1064 nm. We therefore advise holders of a certificate of competence against purchasing long-pulsed diode lasers with wavelengths in the 1064 nm range. This is because of potential risks to clients and potential modifications to the legal framework. This recommendation does not apply to physicians and practice personnel directly instructed by them;
- Treatments using IPL devices that produce non-coherent pulsed radiation with LED rather than flashbulbs, fall under the applicable regulations;
- Treatments using devices that introduce substances for cosmetic purposes into the skin, for example using ultrasound or radiofrequency, fall under the applicable regulations provided they are used for treatments as specified under point 2.1.1;
- Treatments using devices that produce plasma for cosmetic purposes fall under the applicable regulations, provided they are used for treatments as specified under point 2.1.1. This is because their effect is partly brought about by non-ionising radiation generated during plasma production;
- Treatments using devices that produce cold, infrared, LED radiation or EMS for cosmetic purposes fall under the applicable regulations provided they are used for the treatments specified under point 2.1.1.

- In Switzerland there are no NIR or sound limits for devices, compliance with which would allow the professional or commercial treatments under 2.1.1 to be performed without a certificate of competence.
- Devices that are intended for the professional or commercial treatments under point 2.1.1 but are advertised using other terms fall under the applicable regulations (e.g. «skin tightening», which is not mentioned in the O-NIRSA, is a wrinkle treatment)
- Treatments using hyaluronic pens are not covered by the O-NIRSA
- Multifunctional products are devices that use a range of technologies, such as multiple-laser devices. Persons with an appropriate certificate of competence are authorised to use those technologies within such multifunctional products which are intended for the treatments covered by their certificate of competence.

Technologies whose use is subject to medical approval may not be used by persons solely holding a certificate of competence. Unless stipulated otherwise by any other applicable legal provision, technologies within multifunctional products for treatments that do not require a certificate of competence may be freely used (e.g. for muscle development using electromagnetic fields). Such free use does not extend, however, to cases in which the technologies concerned are to be used simultaneously for treatments requiring a certificate of competence (e.g. for muscle development using electromagnetic fields combined with fat burning).

- Microneedling using radio frequencies and needle epilation are not subject to any certificate of competence requirement. They may, however, require the due and full observance of certain cantonal provisions.

4 Prohibited treatments

The following treatments are prohibited:

- The **removal of permanent make up and tattoos using intense pulsed light (IPL)**. The use of such equipment for these treatments does not correspond to current technical and scientific standards and leads to scarring of the skin.
- The **treatment of liver spots (melanocytic naevi) using laser beams or IPL**. Such marks must be removed using suitable surgical methods.

5 Contact

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