



### Factsheets

Information on the  
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[www.bag.admin.ch/  
niss-faktenblaetter](http://www.bag.admin.ch/niss-faktenblaetter)

### Contact

Tel.: 058 462 96 14  
E-Mail: [str@bag.admin.ch](mailto:str@bag.admin.ch)

## 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.

## 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.

**Table 1 Certificates of competence**

<b>Certificate of competence (CC)</b>	<b>Associated treatments</b>
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	Treatment of acne, wrinkles, scars, post-inflammatory hyperpigmentation and stretch marks  Treatment of couperose, haemangiomas and spider naevi measuring less than or equal to 3 mm that are not close to the eyes  <b>Please note:</b> 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
CC cellulite and subcutaneous fat	Treatment of cellulite and subcutaneous fat
CC fungal nail infections	Treatment of fungal nail infections

Physicians and practice personnel directly instructed by them may carry out these treatments without 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.

### **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: The recognition of certificates of competence issued by other countries is being clarified.
- 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

## 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 Transitional regulations until 1 June 2024

### **Use of Class 4 lasers and IPL devices authorised as medical devices by persons without a certificate of competence**

Beauticians with a Federal PET Diploma or equivalent qualification (higher education), or an equivalent basic and further training, can use Class 4 lasers and IPL devices that are authorised as medical devices until 1 June 2024 without a certificate of competence, provided they carry out the treatments under direct medical supervision (in accordance with Annex 6 of the Medical Devices Ordinance of 17 October 2001<sup>1)</sup> MedDO). As soon as such persons have obtained certificates of competence, direct medical supervision is no longer needed. From 1 June 2024, these persons may only perform such treatments if they hold the relevant certificates of competence. These transitional regulations do not apply to people with other vocational qualifications or those without a vocational qualification.

### **Use of low-voltage equipment that generates NIR and sound for cosmetic treatments by persons without a certificate of competence**

For low-voltage equipment, the Product Safety Act makes it compulsory for those providing services (e.g. lasers in a beauty salon) to follow the manufacturer's safety instructions and to ensure there is little or no risk to the health and safety of the person being treated. Under this requirement, products placed on the market as low-voltage electrical equipment may be used until 1 June 2024 without a certificate of competence. On account of their dangerous nature, however, we recommend that such products are used under the same conditions as medical devices.

#### **Please note:**

Please note the [factsheet on the new regulations regarding products for cosmetic treatments using non-ionising radiation and sound](#). It sets out what cosmetic providers such as commercial cosmetics businesses, professional cosmetics schools or doctors should observe with regard to their NIR and sound devices.

## 6 Contact

Federal Office of Public Health FOPH  
Health Protection Directorate  
Non-ionising Radiation and Dosimetry Section  
Schwarzenburgstrasse 157  
CH-3003 Bern

[www.bag.admin.ch/nissg](http://www.bag.admin.ch/nissg)  
[nissg@bag.admin.ch](mailto:nissg@bag.admin.ch)

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<sup>1</sup> SR 812.213