

### Factsheets

Products for cosmetic treatments

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

[Fact Sheets NIR](#)

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## Products for cosmetic treatments using non-ionising radiation and sound

### 1 Background

The following regulations govern the professional and commercial use of devices that produce non-ionising radiation (NIR) and sound for cosmetic purposes (hereinafter referred to as NIR and sound devices):

- The Federal Act on the Protection against the Risks associated with Non-Ionising Radiation and with Sound (NIRSA) and the Ordinance on the Protection against the Risks associated with Non-Ionising Radiation and with Sound (O-NIRSA) have governed the commercial and professional use of NIR and sound devices for cosmetic treatments, but not their placing on the market, since 1 June 2019. The details of these new regulations are described in the factsheet [Use of products for cosmetic purposes](#) of the Federal Office of Public Health FOPH. The FOPH is the competent body in this area.
- From 1 November 2023, the Medical Devices Ordinance (MedDO) of 1 July 2020 governs the placing on the market of a number of non-medical NIR and sound devices, which were previously placed on the market as low-voltage electrical equipment, but this will no longer be permitted from 1 May 2024. The MedDO places more stringent requirements on these products, bringing them into line with medical devices. For non-medical NIR and sound devices that are placed on the market in accordance with the MedDO, Swissmedic is the competent market supervisory authority;
- Under Art. 106 MedDO ([https://www.fedlex.admin.ch/eli/cc/2020/552/de#art\\_106](https://www.fedlex.admin.ch/eli/cc/2020/552/de#art_106)), NIR and sound devices that were previously placed on the market as low-voltage electrical equipment can continue to be marketed under certain conditions during the transitional period;
- NIR and sound devices that were placed on the market by their manufacturers prior to 1 November 2023 under the Medical Devices Ordinance or as low-voltage electrical equipment, may continue to be used for treatments in accordance with the O-NIRSA.

This factsheet describes what cosmetic service providers, such as commercial beauty salons, vocational beauty colleges and physicians need to pay attention to regarding their NIR and sound devices due to these new regulations.

## 2 NIR and sound devices for cosmetic treatments

### 2.1 Products that fall under the MedDO

The placing on the market of certain NIR and sound devices falls under the Medical Devices Ordinance MedDO of 1 July 2020. Article 1 paragraph 1 letter b MedDO in conjunction with Annex 1 MedDO regulates the 'product groups without an intended medical purpose'. Besides other products, this Annex lists the following NIR and sound devices for use on the human body:

- High intensity electromagnetic radiation (e.g. infrared, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment;
- Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

Products must meet the basic safety and performance requirements. Products without an intended medical purpose must comply with the common specifications defined by Swissmedic. Anyone who places products under the MedDO on the market must be able to present a declaration and certificate of conformity on request.

Low-voltage electrical equipment for cosmetic purposes that corresponds to the products listed in Annex 1 to the MedDO may not be placed on the market for the first time from 1 May 2024. However, such low-voltage electrical equipment that was placed on the market prior to 1 May 2024, may continue to be sold in unchanged form during a transitional period until the end of 2028 or the end of 2029. They may not be modified though.

### 2.2 Low-voltage electrical equipment

Low-voltage electrical equipment, which may present the same hazards as identical medical devices, are subject to less stringent safety requirements. No notified body is required for the conformity assessment and issue of a corresponding declaration of conformity for a low-voltage electrical product. The manufacturer can assess its product's compliance with the basic requirements and issue the declaration of conformity itself. A declaration of conformity for low-voltage electrical equipment must satisfy specific criteria: [SR 734.26 – Ordinance of 25 November 2015 on Low-Voltage Electrical Equipment \(LVEO\) \(admin.ch\)](#).

It must:

- a. be written in a Swiss official language or in English, or be translated into one of these languages and
- b. declare the product's conformity with EU law in accordance with Annex IV to the Low Voltage Directive 2014/35/EU and
- c. in each case include at least the following details:
  1. Product or product model, including type, batch or serial number;
  2. Name and address of the manufacturer or their authorised representative in Switzerland;
  3. Description of the low-voltage electrical equipment and information on identification.

Products that generate NIR and sound for cosmetic purposes and that are not listed in Annex 1 to the MedDO can continue to be placed on the market as low-voltage electrical equipment. Such products come under the O-NIRSA provided they are used for the treatments specified in the O-NIRSA.

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<sup>1</sup> End of 2029 if the manufacturer has to carry out in-depth checks on the product – see [COMMISSION IMPLEMENTING REGULATION \(EU\) 2022/2346](#)

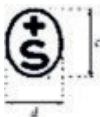
### 3 Process for checking conformity of NIR and sound devices for cosmetic purposes

There are indications that NIR and sound devices with no or falsified declarations of conformity are being traded and used commercially. These products can endanger clients and present a business risk. The process below explains how to check whether your product complies with the applicable requirements.

#### **Step 1: check whether the product in question falls under the MedDO or is a low-voltage electrical product:**

Is evidence of conformity enclosed with the product (declaration of conformity and (for medical devices) a certificate of conformity)?

- No evidence of conformity enclosed: request this evidence of conformity from the manufacturer, importer or seller. If you are unable to obtain this evidence, do not purchase or use the product;
- Evidence of conformity enclosed:
  - o If the evidence of conformity states Regulation (EU) 2017/745 ('MDR') or Directive 93/42/EWG ('MDD'), it is a medical device or product as listed in Annex 1 MedDO.
  - o If the evidence of conformity features the description 2014/35/EU (number of the EU Low-Voltage Directive) or the certification mark of the Federal Inspectorate for Heavy Current Installations, it is a low-voltage electrical product;



- o If the letters described above do not feature in the proof of conformity, it is not advisable to purchase or use the product.

#### **Step 2: check whether the certificate of conformity is valid**

##### **Products that fall under the MedDO:**

A medical device must satisfy strict basic requirements. If it fails to do so, it will not be issued with a

certificate of conformity. These certificates can only be issued by notified bodies following an in-depth inspection of the device or product. Notified bodies are organisations under private law that are under government supervision. To ensure that that your certificate of conformity is genuine, you need two details:

1. The name of the notified body: in the lists of notified bodies under [Regulation \(EU\) 2017/745 on medical devices](#) and the old medical devices legislation 'MDD': [93/42/EEC Medical devices](#), you can look up the website address of the notified body specified on the certificate of conformity and determine whether the notified body is 'active' in the domain in question;
2. The certificate of conformity number: you can enter the certificate of conformity number in the query form on the notified body's website to check that the certificate of conformity is valid<sup>23</sup>.

Alternatively, you can use the contact details of the notified bodies and query forms listed under section 4 of this factsheet, which is based on the sources listed under point 1. If you do not find a certificate of conformity when you enter the number, you can check with the notified body directly whether the certificate is valid. If the certificate of conformity that you have does not meet these requirements, you should not purchase or use the product.

##### **Low-voltage electrical equipment**

As stated in Section 2.1, low-voltage electrical equipment for cosmetic purposes that corresponds to the products listed in Annex 1 to the MedDO may only continue to be sold without the certificate of conformity required under Regulation (EU) 2017/745 (EU-MDR)

until the end of 2028 or the end of 2029 under certain conditions, i.e. that the product concerned was actually and legally marketed in Switzerland before 1 May 2024. Proof of such prior marketing must be provided by the importer of the product concerned in the form of appropriate documentary evidence, such as:

1. a declaration of conformity issued before 1 May 2024, or
2. other documentary proof (such as an invoice or a delivery note dated before 1 May 2024) that the product was actually sold in Switzerland before 1 May 2024.

If these requirements cannot be met, or if the requisite documentary proof cannot be provided, the transitional provisions shall no longer apply to the product

concerned, and the product may no longer be sold in Switzerland.

Additional requirements of the transitional provisions specified in Art. 106 MedDO need not be explicitly verified by the user, but must be met by the importer at the time of marketing. Information on these, particularly for dealers/importers, will be found on Swissmedic's 'Product groups without an intended medical purpose' factsheet, which is available on the Swissmedic website at

<https://www.swissmedic.ch/swissmedic/en/pomz.html>

### **Step 3: consider other important points when purchasing NIR and sound devices**

#### **Products that fall under the MedDO:**

Besides a valid certificate of conformity, the obligations set out in the MedDO need to be considered when purchasing products that fall under the MedDO.

If you do not purchase your equipment from a Swiss retailer, please take note of the Swissmedic factsheets for economic operators and procurement in health institutions, which describe the requirements under the MedDO.

#### **Low-voltage electrical equipment**

Besides a valid certificate of conformity, the following points should also be borne in mind when purchasing low-voltage electrical equipment:

- Make sure the instructions are clear and comprehensible;
- Ensure that the device's network cable has a Swiss plug;
- Make sure if the device bears the voluntary safety mark or the Swiss safety mark issued by the Federal Inspectorate for Heavy Current Installations ESTI. You can also check in the ESTI database to make sure that your device can bear the ESTI safety mark;
- Purchase your equipment from specialised shops in Switzerland, rather than from platforms outside Europe. This way, you can be sure that the device has been imported in accordance with the applicable regulations and that there will be a statutory contact person.

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<sup>2</sup> Under the transitional regulations, certificates of conformity issued under the old MDD legislation are valid until 2027/2028 depending on the classification of the medical device, if the manufacturer has implemented a QM system in accordance with the MDR and signed a written agreement on performance of a conformity assessment for this system by no later than 1 September 2024, and can provide evidence of it. In other words, such products can continue to be sold until 2027/2028 despite expiry of the certificates of conformity provided they were not modified after 1 May 2021.

<sup>3</sup> Since 1 May 2021, notified bodies have no longer been allowed to issue certificates of conformity under the old MDD. There have been no notified bodies for the MDD since this date. Medical devices that were modified after 1 May 2021, must now be certified under the MDR.

## 4 List of notified bodies for medical devices

Body-type	Name and link to address of notified body	Query form or contact for notified body	EU legal frame-work
NB 0044	<a href="#">TÜV NORD CERT GmbH</a>	<a href="#">Zertifikatsdatenbank   Info-Center   TÜV NORD (tuev-nord.de)</a>	MDR / MDD
NB 0050	<a href="#">National Standards Authority of Ireland (NSAI)</a>	<a href="#">NSAI   Certified company search   NSAI</a>	MDR / MDD
NB 0051	<a href="#">IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.</a>	<a href="#">Certified products database – IMQ</a>	MDR / MDD
NB 0068	<a href="#">MTIC InterCert S.r.l.</a>	<a href="#">Certificates Databases   MTIC Group (mtic-group.org)</a>	MDD
NB 0123	<a href="#">TÜV SÜD Product Service GmbH</a>	<a href="#">Zertifikatsdatenbank   TÜV SÜD (tuvsud.com)</a> <a href="#">Schwarze Liste mit gefälschten Zertifikaten Schwarze Liste – Prüfzeichenmissbräuche   TÜV SÜD (tuvsud.com)</a>	MDR / MDD
NB 0124	<a href="#">DEKRA Certification GmbH</a>	<a href="#">DEKRA Check.me (dekra-checkme.com)</a>	MDR / MDD
NB 0197	<a href="#">TÜV Rheinland LGA Products GmbH</a>	<a href="#">Certipedia – Zertifikatsdatenbank von TÜV Rheinland</a>	MDR / MDD
NB 0297	<a href="#">DQS Medizinprodukte GmbH</a>	<a href="#">Zertifikatsvalidierung und Zertifikatscheck   DQS (dqs-global.com)</a>	MDR / MDD
NB 0318	<a href="#">CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS</a>	<a href="#">Organismo notificado 0318   Centro Nacional de Certificación de Productos Sanitarios (certificaps.gob.es)</a>	MDR / MDD
NB 0344	<a href="#">DEKRA Certification B.V.</a>	<a href="#">DEKRA Check.me (dekra-checkme.com)</a>	MDR / MDD
NB 0373	<a href="#">ISTITUTO SUPERIORE DI SANITA'</a>	<a href="#">Notified Body – ISS (EN) – ISS</a>	MDR / MDD
Body-type	Name and link to address of notified body	Query form or contact for notified body	EU legal frame-work
NB 0402	<a href="#">RISE Research Institutes of Sweden AB</a>	<a href="#">publiccert.ri.se/en/Product/List/</a>	MDD
NB 0413	<a href="#">INTERTEK SEMKO AB</a>	<a href="#">Home Page - CertificateDirectory (intertek.se)</a>	MDD
NB 0425	<a href="#">ICIM S.P.A.</a>	Keine Suchmaske, direkt anfragen	MDR / MDD
NB 0426	<a href="#">ITALCERT SRL</a>	Keine Suchmaske, direkt anfragen	MDR / MDD
NB 0459	<a href="#">GMED SAS</a>	<a href="#">Certificate Repository - GMED Medical Device Certification (lne-gmed.com)</a>	MDR / MDD
NB 0476	<a href="#">KIWA CERMET ITALIA S.P.A.</a>	<a href="#">Research your Kiwa Certificate</a>	MDR / MDD
NB 0477	<a href="#">Eurofins Product Testing Italy S.r.l.</a>	<a href="#">Kundenportal   Eurofins E&amp;E</a>	MDR / MDD
NB 0482	<a href="#">DNV MEDCERT GmbH</a>	<a href="#">DNV - Find a valid certificate</a>	MDR / MDD
NB 0483	<a href="#">MDC MEDICAL DEVICE CERTIFICATION GMBH</a>	<a href="#">mdc medical device certification GmbH - Listen der Zertifikate (mdc-ce.de)</a>	MDR / MDD

NB 0494	<a href="#">SLG PRÜF UND ZERTIFIZIERUNGS GMBH</a>	Keine Suchmaske, direkt anfragen	MDR / MDD
NB 0537	<a href="#">Eurofins Electric &amp; Electronics Finland Oy</a>	<a href="#">Sertifikaattihaku</a>	MDR / MDD
NB 0546	<a href="#">CERTIQUALITY S.r.l.</a>	<a href="#">They have chosen us   Certiquality</a>	MDR / MDD
NB 0598 ex:403	<a href="#">SGS FIMKO OY</a>	<a href="#">Verify SGS Documents   SGS Finland</a>	MDR / MDD
NB 0633	<a href="#">Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH</a>	<a href="#">Gültigkeitsprüfung einer Zertifizierung - Berlin Cert GmbH</a>	MDR / MDD
NB 0653	<a href="#">NATIONAL EVALUATION CENTER OF QUALITY AND TECHNOLOGY IN HEALTH S.A.- EKAPTY</a>	<a href="#">Home page   EKAPTY ERP</a>	MDD
NB 0681	<a href="#">Eurofins Product Service GmbH</a>	<a href="#">Eurofins Medical Device Testing - Eurofins Deutschland</a>	MDD
NB 1011	<a href="#">NEOEMKI Nemzeti Orvostechikai Eszköz Megfelelőségértékelő és Tanúsító Korlátolt Felelősségű Társaság (NEO-EM-KI LLC)</a>	Keine Suchmaske, direkt anfragen	MDD
NB 1014	<a href="#">ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV, s.p.</a>	<a href="#">EZÚ VHPTZ (ezu.cz)</a>	MDD
NB 1023	<a href="#">INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s. (INSTITUTE FOR TESTING AND CERTIFICATION) merged with ex-NB 1390</a>	<a href="#">ITC – institut pro testování a certifikace (itczlin.cz)</a>	MDR / MDD
NB 1282	<a href="#">ENTE CERTIFICAZIONE MACCHINE SRL</a>	<a href="#">Verifica Certificato – Ente Certificazione Macchine (entecerma.it)</a>	MDR / MDD
NB 1304	<a href="#">SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ</a>	<a href="#">Certificates Search - SIQ</a>	MDR / MDD
NB 1370	<a href="#">BUREAU VERITAS ITALIA S.P.A.</a>	Keine Suchmaske, direkt anfragen	MDR / MDD
<b>Body-type</b>	<b>Name and link to address of notified body</b>	<b>Query form or contact for notified body</b>	<b>EU legal frame-work</b>
NB 1434	<a href="#">POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.</a>	<a href="#">PCBC - Wyszukiwarka certyfikatów</a>	MDR / MDD
NB 1639	<a href="#">SGS Belgium NV</a>	<a href="#">SGS Certified Components and Products   SGS Czech Republic (sgsgroup.cz)</a>	MDR / MDD
NB 1783	<a href="#">TURKISH STANDARDS INSTITUTION (TSE)</a>	<a href="#">TSE Belgelendirilmiş Firma Arama/Sorgulama</a>	MDD
NB 1912	<a href="#">Kiwa Dare B.V.</a>	<a href="#">EZÚ VHPTZ (ezu.cz)</a>	MDR / MDD
NB 1936	<a href="#">TUV Rheinland Italia SRL</a>	<a href="#">Product Manufacturers from A-Z - Certipedia</a>	MDR / MDD
NB 1984	<a href="#">Kiwa Belgelendirme Hizmetleri A.Ş.</a>	<a href="#">Certificate Search Page for Kiwa Turkey</a>	MDD
NB 2195	<a href="#">Szutest Uygunluk Değerlendirme A.Ş.</a>	<a href="#">SZUTEST Portal</a>	MDD
NB 2265	<a href="#">3EC International a.s.</a>	Keine Suchmaske, direkt anfragen	MDR / MDD
NB 2274	<a href="#">TUV NORD Polska Sp. z o.o</a>	<a href="#">Zertifikatsdatenbank   Info-Center   TÜV NORD (tuev-nord.de)</a>	MDR / MDD

NB 2292	<a href="#"><u>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.</u></a>	<a href="#"><u>Belge Sorgula - UDEM System and Product Certification Services</u></a>	MDD
NB 2409	<a href="#"><u>CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.</u></a>	<a href="#"><u>Certificate information – CE Certiso</u></a>	MDR / MDD
NB 2460	<a href="#"><u>DNV Product Assurance AS</u></a>	<a href="#"><u>DNV - Find a valid certificate</u></a>	MDR / MDD
NB 2696	<a href="#"><u>UDEM Adriatic d.o.o.</u></a>	<a href="#"><u>UDEM Adriatic D.O.O.</u></a>	MDR
NB 2764	<a href="#"><u>Notice Belgelendirme, Muayene ve Denetim Hizmetleri Anonim Şirketi</u></a>	<a href="#"><u>Notice Belgelendirme Muayene ve Denetim Hizmetleri A.Ş - Tecrübelerimiz ile geleceği kuruyoruz.</u></a>	MDD
NB 2797	<a href="#"><u>BSI Group The Netherlands B.V.</u></a>	<a href="#"><u>BSI-issued certificates and verifications, directories   BSI (bsigroup.com)</u></a>	MDR / MDD
NB 2803	<a href="#"><u>HTCert (Health Technology Certification Ltd)</u></a>	<a href="#"><u>Medical Device Directive Certified Clients – HTCert System</u></a>	MDR / MDD
NB 2854	<a href="#"><u>bqs. s.r.o.</u></a>	<a href="#"><u>Certified clients directory - bqs. certification body (bqsgroup.eu)</u></a>	MDD
NB 2862	<a href="#"><u>Intertek Medical Notified Body AB</u></a>	<a href="#"><u>Business Assurance Certificate Validation (intertek.com)</u></a>	MDR
NB 2975	<a href="#"><u>SZUTEST Konformitätsbewertungsstelle GmbH</u></a>	<a href="#"><u>SZUTEST Konformitätsbewertungsstelle GmbH - szutest-germany.de</u></a>	MDR