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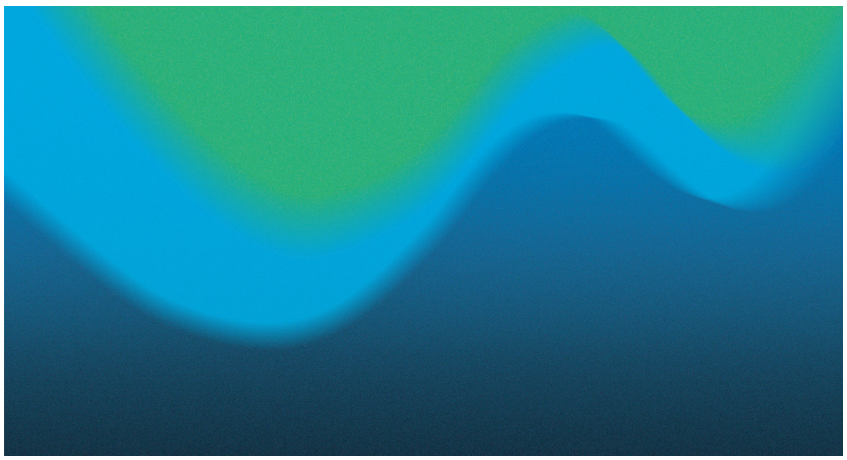

Factsheets
Products for cosmetic treatments
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www.bag.admin.ch/Fact Sheets NIR

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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), 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 andd
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.

[1] End of 2029 if the manufacturer has to carry out in-depth checks on the product – see COMMISSION IMPLE-MENTING 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. 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[2][3].

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
You can determine when the manufacturer placed the low-voltage electrical equipment on the market from the date on the certificate of conformity. If this date is prior to 1 May 2024, the device can continue to be sold. If it is after 1 May 2024, it can no longer be legally placed on the market for the first time as a low-voltage electrical device, which means you should not purchase or use it. If the low-voltage electrical equipment was legally placed on the market, you can continue to use it for cosmetic treatments.

2 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 assess-ment 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.

3 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.

Step 3: consider other important points when purchasing NIR and sound devic-es

Products that fall under the MedDO:
Besides a valid certificate of conformity, the obligations set out in the MedDO need to 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.

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	TÜV NORD CERT GmbH	Zertifikatsdatenbank | Info-Center | TÜV NORD (tuev-nord.de)	MDR / MDD
NB 0050	National Standards Authority of Ireland (NSAI)	NSAI | Certified company search | NSAI	MDR / MDD
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Certified products database – IMQ	MDR / MDD
NB 0068	MTIC InterCert S.r.l.	Certificates Databases | MTIC Group (mtic-group.org)	MDD
NB 0123	TÜV SÜD Product Service GmbH	Zertifikatsdatenbank | TÜV SÜD (tuvsud.com) Schwarze Liste mit gefälschten Zertifi-katen Schwarze Liste – Prüfzeichenmissbräuche | TÜV SÜD (tuvsud.com)	MDR / MDD
NB 0124	DEKRA Certification GmbH	DEKRA Check.me (dekra-checkme.com)	MDR / MDD
NB 0197	TÜV Rheinland LGA Products GmbH	Certipedia – Zertifikatsdatenbank von TÜV Rheinland	MDR / MDD
NB 0297	DQS Medizinprodukte GmbH	Zertifikatsvalidierung und Zertifikatscheck | DQS (dqs-global.com)	MDR / MDD
NB 0318	CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS	Organismo notificado 0318 | Centro Nacional de Certificación de Productos Sanitarios (certificaps.gob.es)	MDR / MDD
NB 0344	DEKRA Certification B.V.	DEKRA Check.me (dekra-checkme.com)	MDR / MDD
NB 0373	ISTITUTO SUPERIORE DI SANITA'	Notified Body – ISS (EN) – ISS	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	RISE Research Institutes of Sweden AB	publiccert.ri.se/en/Product/List/	MDD
NB 0413	INTERTEK SEMKO AB	Home Page - CertificateDirectory (intertek.se)	MDD
NB 0425	ICIM S.P.A.	Keine Suchmaske, direkt anfragen	MDR / MDD
NB 0426	ITALCERT SRL	Keine Suchmaske, direkt anfragen	MDR / MDD
NB 0459	GMED SAS	Certificate Repository - GMED Me-dical Device Certifi-cation (lne-gmed.com)	MDR / MDD
NB 0476	KIWA CERMET ITALIA S.P.A.	Research your Kiwa Certificate	MDR / MDD
NB 0477	Eurofins Product Testing Italy S.r.l.	Kundenportal | Eurofins E&E	MDR / MDD
NB 0482	DNV MEDCERT GmbH	DNV - Find a valid certificate	MDR / MDD
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	mdc medical device certification GmbH - Listen der Zer-tifikate (mdc-ce.de)	MDR / MDD
NB 0494	SLG PRÜF UND ZERTIFIZIERUNGS GMBH	Keine Suchmaske, direkt anfragen	MDR / MDD
NB 0537	Eurofins Electric & Electronics Finland Oy	Sertifikaattihaku	MDR / MDD
NB 0546	CERTIQUALITY S.r.l.	They have chosen us | Certiquality	MDR / MDD
NB 0598 ex:403	SGS FIMKO OY	Verify SGS Documents | SGS Finland	MDR / MDD
NB 0633	Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH	Gültigkeitsprüfung einer Zertifizierung - Berlin Cert GmbH	MDR / MDD
NB 0653	NATIONAL EVALUATION CENTER OF QUALITY AND TECHNOLOGY IN HEALTH S.A.- EKAPTY	Home page | EKAPTY ERP	MDD
NB 0681	Eurofins Product Service GmbH	Eurofins Medical Device Testing - Eurofins Deutschland	MDD
NB 1011	NEOEMKI Nemzeti Orvostechnikai Es-zköz Megfelelőségértékelő és Tanúsító Korlátolt Felelősségű Társaság (NEO-EM-KI LLC)	Keine Suchmaske, direkt anfragen	MDD
NB 1014	ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV, s.p.	EZÚ VHPTZ (ezu.cz)	MDD
NB 1023	INSTITUT PRO TESTOVÁNI A CER-TIFIKA-CI, a. s. (INSTITUTE FOR TESTING AND CERTIFICATION) merged with ex-NB 1390	ITC – institut pro testování a certifikace (itczlin.cz)	MDR / MDD
NB 1282	ENTE CERTIFICAZIONE MACCHINE SRL	Verifica Certifiato – Ente Certificazione Macchine (entecerma.it)	MDR / MDD
NB 1304	SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ	Certificates Search - SIQ	MDR / MDD
NB 1370	BUREAU VERITAS ITALIA S.P.A.	Keine Suchmaske, direkt anfragen	MDR / MDD

Body-type	Name and link to address of notified body	Query form or contact for notified body	EU legal frame-work
NB 1434	POLSKIE CENTRUM BADAN I CER-TYFI-KACJI S.A.	PCBC - Wyszukiwarka certyfikatów	MDR / MDD
NB 1639	SGS Belgium NV	SGS Certified Components and Products | SGS Czech Republic (sgsgroup.cz)	MDR / MDD
NB 1783	TURKISH STANDARDS INSTITUTION (TSE)	TSE Belgelendirilmiş Firma Arama/Sorgulama	MDD
NB 1912	Kiwa Dare B.V.	EZÚ VHPTZ (ezu.cz)	MDR / MDD
NB 1936	TUV Rheinland Italia SRL	Product Manufacturers from A-Z - Certipedia	MDR / MDD
NB 1984	Kiwa Belgelendirme Hizmetleri A.Ş.	Certificate Search Page for Kiwa Turkey	MDD
NB 2195	Szutest Uygunluk Değerlendirme A.Ş.	SZUTEST Portal	MDD
NB 2265	3EC International a.s.	Keine Suchmaske, direkt anfragen	MDR / MDD
NB 2274	TUV NORD Polska Sp. z o.o	Zertifikatsdatenbank | Info-Center | TÜV NORD (tuev-nord.de)	MDR / MDD
NB 2292	UDEM Uluslararasi Belgelendirme De-netim Egitim Merkezi San. ve Tic. A.Ş.	Belge Sorgula - UDEM System and Product Certification Services	MDD
NB 2409	CE Certiso Orvos- és Kórháztechnikai El-lenőrző és Tanúsító Kft.	Certificate information – CE Certiso	MDR / MDD
NB 2460	DNV Product Assurance AS	DNV - Find a valid certificate	MDR / MDD
NB 2696	UDEM Adriatic d.o.o.	UDEM Adriatic D.O.O.	MDR
NB 2764	Notice Belgelendirme, Muayene ve De-netim Hizmetleri Anonim Şirketi	Notice Belgelendirme Muayene ve Denetim Hizmetleri A.Ş - Tecrübelerimiz ile geleceği kuruyoruz.	MDD
NB 2797	BSI Group The Netherlands B.V.	BSI-issued certificates and verifica-tions, directories | BSI (bsigroup.com)	MDR / MDD
NB 2803	HTCert (Health Technology Certification Ltd)	Medical Device Directive Certified Clients – HTCert System	MDR / MDD
NB 2854	bqs. s.r.o.	Certified clients directory - bqs. certification body (bqsgroup.eu)	MDD
NB 2862	Intertek Medical Notified Body AB	Business Assurance Certificate Validation (intertek.com)	MDR
NB 2975	SZUTEST Konformitätsbewertungsstelle GmbH	SZUTEST Konformitätsbewertungsstelle GmbH - szutest-germany.de	MDR