

99003056000000

Display operation of facilities for the application of non-ionising radiation to humans for cosmetic or other non-medical purposes

Heruntergeladen am 02.06.2025

<https://fimportal.de/xzufi-services/6010993/L100022>

Modul	Sachverhalt
Leistungsschlüssel	99003056000000
Leistungsbezeichnung I	Display operation of facilities for the application of non-ionising radiation to humans for cosmetic or other non-medical purposes
Leistungsbezeichnung II	Display operation of facilities for the application of non-ionising radiation to humans for cosmetic or other non-medical purposes
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Baden-Württemberg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	

Modul	Sachverhalt
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	
Fachlich freigegeben durch	
Handlungsgrundlage	<p>[Verordnung zum Schutz vor schädlichen Wirkungen nichtionisierender Strahlung bei der Anwendung am Menschen (NiSV):](https://www.gesetze-im-internet.de/nisv/)</p> <ul style="list-style-type: none"> • § 3 Allgemeine Anforderungen an den Betrieb • § 4 Fachkunde • § 4a Nachweis der Fachkunde • § 13 Übergangsregelungen
Teaser	<p>If you wish to commercially operate equipment for the application of non-ionising radiation to humans for cosmetic or other non-medical purposes, you must notify the competent authority.</p>
Volltext	<p>If you wish to commercially operate equipment for the application of non-ionising radiation to humans for cosmetic or other non-medical purposes, you must notify the competent authority.</p> <p>Non-medical use means that the use is not for the purpose of examining and treating a patient, early detection of diseases, prenatal care or medical research.</p> <p>The devices concerned may include</p> <ul style="list-style-type: none"> • Ultrasound devices • Laser devices • intense light sources emitting intense pulsed or non-pulsed incoherent optical radiation

Modul

Sachverhalt

- High-frequency devices
- Low-frequency devices
- Direct current devices
- Magnetic field devices

are included. The power specifications are given in the definitions of the Ordinance on Protection against Harmful Effects of Non-Ionising Radiation when Used on Humans (NiSV). If you do not know the performance characteristics or cannot find them in the documentation for your system, please contact your dealer or the manufacturer of your system.

Certain applications may only be carried out by authorised physicians with appropriate training or further training (see Notes section).

Erforderliche Unterlagen

The following information and documents are required for the notification of the operation of an installation for the application of non-ionising radiation:

- Details of the system operator
- Information on the system (e.g. manufacturer, serial number, model, type) and information on the application
- Details of the persons using the equipment
- proof of specialist knowledge or training (see Notes section)
- for doctors: Proof of further medical training or advanced training

Voraussetzungen

Persons using the system must have the necessary expertise. Expertise can be acquired through successful participation in a suitable training course or through suitable initial or further training.

Kosten

none

Verfahrensablauf

After you have notified the operation of a non-ionising radiation facility, the competent authority will check it and request documents if necessary. Depending on the services offered by the competent authority, you may be provided with a form or an online process.

Modul	Sachverhalt
Bearbeitungsdauer	
Frist	The operator must notify the system at least two weeks before the planned commissioning.
weiterführende Informationen	
Hinweise	<p>The following treatments may only be carried out by licensed physicians with appropriate further training or advanced training:</p> <ul style="list-style-type: none"> • Laser applications <ul style="list-style-type: none"> • for the removal of tattoos or permanent make-up • for the treatment of vascular changes • for the treatment of pigmented skin changes (e.g. moles, birthmarks, age spots) <ul style="list-style-type: none"> • where the integrity of the epidermis (epidermis) as a protective barrier is damaged • ablative (removal of tissue layers) • Applications with optical radiation whose effects are not limited to the skin and its appendages, such as fatty tissue reduction <ul style="list-style-type: none"> • High frequency applications <ul style="list-style-type: none"> • in which the integrity of the epidermis (epidermis) as a protective barrier is violated • which are used for the thermal reduction of fatty tissue or the treatment of vascular changes or pigmented skin changes • Applications to stimulate the central nervous system • Applications <ul style="list-style-type: none"> • focussed ultrasound, in which the integrity of the epidermis as a protective barrier is violated <ul style="list-style-type: none"> • ultrasound for targeted thermal tissue coagulation or fatty tissue reduction • Use of magnetic resonance imaging for non-medical purposes <p>In the event that specialist knowledge has been acquired through participation in suitable training, proof of specialist knowledge has been provided to the competent authority in the form of a certificate since 1 January 2024. If in doubt, clarify with the competent</p>

Modul	Sachverhalt
	authority whether the transitional provisions of Section 13 (2) to (4) of the Ordinance on Protection against Harmful Effects of Non-Ionising Radiation when Used on Humans (NiSV) are relevant.
Rechtsbehelf	none
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	