

99003056261000, 99003056261000

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

Heruntergeladen am 07.06.2025

<https://fimportal.de/xzufi-services/132144924/L100027>

Modul	Sachverhalt
Leistungsschlüssel	99003056261000, 99003056261000
Leistungsbezeichnung I	Display operation of facilities for the application of non-ionizing radiation to humans for cosmetic or other non-medical purposes
Leistungsbezeichnung II	
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug, 2b - Bundesauftragsverwaltung: Regelung, Land: Ausführungsvorschriften, Kommune: Vollzug
Quellredaktion	Mecklenburg-Vorpommern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	fachlich freigegeben (silber)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung

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Leistungsgruppierung	Gesundheit (003)
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	03.11.2023
Fachlich freigegeben durch	Ministry of Social Affairs, Health and Sport Mecklenburg-Vorpommern
Handlungsgrundlage	
Teaser	Do you want to use a system for the application of non-ionizing radiation to humans, for cosmetic or other non-medical purposes? Then you must notify the competent authority of this equipment at least two weeks before commissioning.
Volltext	The Ordinance on Protection against Harmful Effects of Non-Ionizing Radiation when Used on Humans (NiSV) regulates the commercial operation of laser devices, intense light sources, high-frequency devices, electrical nerve and muscle stimulation devices, magnetic field stimulation devices, central nervous system stimulation devices and ultrasound devices. Anyone using these devices commercially for cosmetic and other non-medical purposes has had to meet new operating requirements as well as documentation and consultation obligations since the start of 2021. In addition, the operation of devices used must be reported to the competent authority. The operation of the respective device must be reported to the competent authority at least two weeks before commissioning. Some applications may only be carried out by licensed doctors with appropriate further training and

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	education (doctor's proviso). The NiSV requires proof of the relevant specialist knowledge for applications that are not subject to a doctor's reservation. The specific requirements for acquiring the necessary specialist knowledge are set out in the NiSV and in detail in the joint federal and state guidelines (Fachkunderichtlinie).
Erforderliche Unterlagen	• Completed form that you can send by post or digitally • license to practice medicine • Proof of professional suitability • Proof of suitable further medical training
Voraussetzungen	• Persons who operate and use the system must have the required specialist knowledge. • In addition, you must notify the competent authority of the operation of the system at least two weeks before the planned commissioning.
Kosten	none
Verfahrensablauf	The notification must state the name or company name of the operator as well as the address of the operating site and the identification details of the respective system. The notification must be accompanied by proof that you or the person using the system has the necessary specialist knowledge. After 14 days, the system can be put into operation unless the competent authority notifies you to the contrary.
Bearbeitungsdauer	1 - 14 Werktag(e)
Frist	2 Woche(n) Before commissioning 3 Jahr(e)
weiterführende Informationen	https://www.lagus.mv-regierung.de/Arbeitsschutz/Strahlenschutz/Anwendung_nichtionisierender_Strahlung/ https://www.lagus.mv-regierung.de/Arbeitsschutz/Strahlenschutz/Anwendung_nichtionisierender_Strahlung/

Modul

Sachverhalt

Hinweise

From December 31, 2020, the following treatments may only be carried out by licensed physicians with appropriate further medical training or advanced training:

- Removal of tattoos or permanent make-up
- Treatment of vascular changes and pigmented skin changes
- Treatments that damage the integrity of the epidermis as a protective barrier
- Applications with optical radiation, high frequency or ultrasound, the effects of which are not limited to the skin and its appendages
- Stimulation of the central nervous system
- Fat tissue reduction
- Ablative laser applications
- Magnetic resonance procedures

Rechtsbehelf

- If your notification is rejected by the authority, this constitutes an administrative act against which you can lodge an appeal.
- Appeal

Kurztext

- Notification of the operation of installations for the application of non-ionizing radiation to humans for cosmetic or other non-medical purposes; receipt
- Operation of equipment for the application of non-ionizing radiation to humans that is used for cosmetic or other non-medical purposes for commercial or other economic purposes.
- An application is non-medical if it does not serve the purpose of examining and treating patients, the early detection of diseases, prenatal care or medical research.
- The operation of such systems is subject to notification.
- Notification online or in writing
- Responsible:
 - for healthcare facilities: State Office for Health and Social Affairs (LAGuS)
 - outside of healthcare facilities: Local health authorities

Ansprechpunkt

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Zuständige Stelle	**At this point, a selection must be made to determine the body ultimately responsible.** **Does the application take place in a healthcare facility?** • If "Yes", click on "Continue **with State Office for Health and Social Affairs (LAGuS)**" • If "No", click on "Continue**with locally responsible health authority**" https://mv-serviceportal.de/leistung/?leistungId=132144924&kategoriId=132476484 https://mv-serviceportal.de/leistung/?leistungId=132144924&kategoriId=132476485 https://mv-serviceportal.de/leistung/?leistungId=132144924&kategoriId=132476484 https://mv-serviceportal.de/leistung/?leistungId=132144924&kategoriId=132476485
Formulare	• Forms available: Yes • Written form required: No • Informal application possible: No • Personal appearance necessary: No
Ursprungsportal	Display operation of facilities for the application of non-ionizing radiation to humans for cosmetic or other non-medical purposes, Betrieb von Anlagen zur Anwendung nichtionisierender Strahlung am Menschen zu kosmetischen oder sonstigen nichtmedizinischen Zwecken anzeigen