

99006018001003, 99006018001003

Display operation or significant change in operation of dental, medical and veterinary X-ray equipment

Heruntergeladen am 21.06.2025

<https://fimportal.de/xzufi-services/410387529/L100008>

Modul	Sachverhalt
Leistungsschlüssel	99006018001003, 99006018001003
Leistungsbezeichnung I	Display operation or significant change in operation of dental, medical and veterinary X-ray equipment
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Sachsen-Anhalt
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arbeitsschutz (006)

Modul	Sachverhalt
Verrichtungskennung	Erteilung (001)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	Prüfung und Nachweise für Sachkunde und Sicherheit (2120300), Anlagenbetrieb und -prüfung (2120100), Anmeldepflichten (2010100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	12.09.2024
Fachlich freigegeben durch	Ministry of Labor, Social Affairs, Health and Equality of the State of Saxony-Anhalt
Handlungsgrundlage	https://www.gesetze-im-internet.de/strlschg/_19.html https://www.gesetze-im-internet.de/strlschg/_19.html
Teaser	If you intend to operate or significantly modify a dental, medical or veterinary X-ray facility and this is not subject to approval, you are obliged to notify the competent authority.
Volltext	With the written notification of a dental, medical or veterinary X-ray facility, you declare that you intend to operate or significantly modify such a facility.
Erforderliche Unterlagen	• Proof of expertise in radiation protection according to StrlSchV with proof of updating • Certificate and test report from the expert on the radiation protection test • Type approval certificate with confirmation of routine testing (if applicable) (type approval = for device in general; confirmation of routine testing = for the specific device) • CE certificate of conformity (if applicable) • Personnel deployment, i.e. proof of knowledge of radiation protection and updates of this knowledge for personnel working on the X-ray equipment
Voraussetzungen	You want to either

Modul

Sachverhalt

1. operate an X-ray device
 - a) whose X-ray source is type-approved,
 - b) the manufacture and first placing on the market of which falls within the scope of the Medical Devices Act, or
 - c) the manufacture and placing on the market of which falls within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1; L 117, 3.5.2019, p. 9; L 334, 27.12.2019, p. 165),
 - d) which has been placed on the market for the first time in accordance with the provisions of the Medical Devices Act and is not used in connection with medical exposures; or
2. you wish to operate a basic, high or full protection device or a school X-ray device; or
3. you wish to substantially modify the operation of such a notified X-ray device and you have a license.

Kosten

Verfahrensablauf

- You submit a written notification to the competent authority. In it, you declare whether you are operating or significantly modifying dental, medical and veterinary X-ray equipment.
- The notification must be submitted before the X-ray equipment is put into operation or significantly modified.
- The competent authority will check the documents and send you a confirmation of notification.

Bearbeitungsdauer

2 - 4 Woche(n)

Modul	Sachverhalt
	Depending on the scope of the application and completeness of the documents. Usually 2-4 weeks.
Frist	4 Woche(n) Before commissioning the X-ray equipment
weiterführende Informationen	https://verbraucherschutz.sachsen-anhalt.de/arbeitschutz/strahlenschutz https://verbraucherschutz.sachsen-anhalt.de/arbeitschutz/strahlenschutz
Hinweise	There are no indications or special features.
Rechtsbehelf	
Kurztext	• Operation of an X-ray facility or significant change to the operation Acceptance for dental, medical or veterinary X-ray facilities • Notification in writing or online • Responsible: Saxony-Anhalt State Office for Consumer Protection (Department 51.4 Radiation Protection)
Ansprechpunkt	State Office for Consumer Protection Saxony-Anhalt - Department 51.4 Radiation protection
Zuständige Stelle	
Formulare	Forms available: Yes Written form required: Yes Informal application possible: No Personal appearance necessary: No
Ursprungsportal	Display operation or significant change in operation of dental, medical and veterinary X-ray equipment, Betrieb oder wesentliche Änderung des Betriebs einer zahnmedizinischen, medizinischen und tiermedizinischen Röntgeneinrichtung anzeigen