

99006018001003, 99006018001003

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

Heruntergeladen am 25.05.2025

<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)

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- 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

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.

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- 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)
 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

Modul	Sachverhalt
	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