

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/278253584/L100012>

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	Schleswig-Holstein
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	Erlaubnisse und Genehmigungen (2010400), Anlagenbetrieb und -prüfung (2120100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	06.04.2022
Fachlich freigegeben durch	The Radiation Protection Department in the Ministry for Energy Transition, Climate Protection, Environment and Nature of the State of Schleswig-Holstein
Handlungsgrundlage	https://www.gesetze-im-internet.de/r_v_1987/_17a.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 in accordance with the Radiation Protection Ordinance with proof of updating • Certificate and test report from the expert(s) on the radiation protection test • Type approval certificate with unit test confirmation (if applicable) (type approval = for device in general; unit test confirmation = 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 • operate an X-ray unit, • whose X-ray source is type-approved in accordance with § 45 paragraph 1 number 2,

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- the manufacture and first placing on the market of which falls within the scope of the Medical Devices Act, or
- 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)
- 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

- you wish to operate a basic, high or full protection device or a school X-ray device; or
- substantially change the operation of such a notified X-ray device and you have a license in accordance with §15 StrISchG.

Kosten

Gebühr: 100€ - 2.500€

Verfahrensablauf

- You submit a written notification to the competent authority. In it, you declare whether you are operating or significantly modifying dental, medical or 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 notification confirmation with a fee notice.

Bearbeitungsdauer

 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

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Hinweise	https://www.schleswig-holstein.de/DE/landesregierung/themen/gesundheitsverbraucherschutz/strahlenschutz/strahlenschutz.html https://www.schleswig-holstein.de/DE/fachinhalte/R/reaktorsicherheit/Downloads/merkblattRoentgenanlagen.pdf?__blob=publicationFile&v=1 https://www.schleswig-holstein.de/DE/landesregierung/themen/gesundheitsverbraucherschutz/strahlenschutz/strahlenschutz.html https://www.schleswig-holstein.de/DE/fachinhalte/R/reaktorsicherheit/Downloads/merkblattRoentgenanlagen.pdf?__blob=publicationFile&v=1
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: Radiation Protection Department in the Ministry for Energy Transition, Climate Protection, Environment and Nature of the State of Schleswig-Holstein
Ansprechpunkt	
Zuständige Stelle	The Radiation Protection Department in the Ministry for Energy Transition, Climate Protection, Environment and Nature of the State of Schleswig-Holstein
Formulare	https://www.schleswig-holstein.de/DE/Fachinhalte/R/reaktorsicherheit/Downloads/anzeigeRoeV.pdf?__blob=publicationFile&v=4+ https://www.schleswig-holstein.de/DE/Fachinhalte/R/reaktorsicherheit/Downloads/anzeigeRoeV.pdf?__blob=publicationFile&v=4+
Ursprungsportal	Betrieb oder wesentliche Änderung des Betriebs einer zahnmedizinischen, medizinischen und tiermedizinischen Röntgeneinrichtung anzeigen, Display operation or significant change in operation of dental, medical and veterinary X-ray equipment