99050178012002, 99050178012002

Apply for certificates of free sale for active in-vitro diagnostics

Heruntergeladen am 23.06.2025
https://fimportal.de/xzufi-services/255616023/L100039

Modul	Sachverhalt
Leistungsschlüssel	99050178012002, 99050178012002
Leistungsbezeichnung I	Apply for certificates of free sale for active in-vitro diagnostics
Leistungsbezeichnung II	Apply for certificates of free sale for active in-vitro diagnostics
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Rheinland-Pfalz
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	fachlich freigegeben (silber)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Gewerbe (050)
Verrichtungskennung	Ausstellung (012)
SDG-Informationsbereich	Feststellung der geltenden Normen, technischen Spezifikationen und Zertifizierung der Produkte
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Import

Modul	Sachverhalt
	und Export (2070200)
Einheitlicher Ansprechpartner	Ja
Fachlich freigegeben am	30.01.2023
Fachlich freigegen durch	Ministry of Science and Health Rhineland-Palatinate
Handlungsgrundlage	https://www.gesetze-im-internet.de/mpdg/ https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0745 https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0746 https://www.gesetze-im-internet.de/mpdg/ https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0745 https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0746
Teaser	As a manufacturer of in vitro diagnostic medical devices that are associated with an active medical device, or its authorized representative, you can apply for the issue of a certificate of free sale for export purposes.
Volltext	Are you responsible for placing an active in-vitro diagnostic medical device on the market and would like to export it outside the Union? Then the relevant competent authority will issue a certificate upon your request. This certificate certifies that the product may be traded in the Union.
Erforderliche Unterlagen	• Declaration of conformity of the medical device concerned • Certificate(s) from the Notified Body(ies) of the medical device concerned • Certification of the manufacturer's quality management by a notified body • Product list in accordance with the IVDR
Voraussetzungen	• Your establishment is located in the area of responsibility of the relevant authority and you are registered in Eudamed.

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	• Your medical devices concerned are registered in DMIDS. • There are no known concerns on the part of the authority. • Current documentation of the medical devices concerned is available.
Kosten	Gebühr: 100€ - 1.000€ https://landesrecht.rlp.de/bsrp/document/jlr-MPRKostVRPrahmen
Verfahrensablauf	1. You submit your application. 2. The competent authority checks the documents. 3. The competent authority requests additional documents if necessary. 4. If all requirements are met, the competent authority issues the certificate of free sale
Bearbeitungsdauer	1 - 3 Woche(n)
Frist	There are no deadlines for the application.
weiterführende Informationen	
Hinweise	
Rechtsbehelf	Objection under the Administrative Procedure Act (VwvVfG) against the charging of fees
Kurztext	• Certificates of free sale for export purposes of medical devices Exhibition For in vitro diagnostics - active • Certificates of free sale are issued for in vitro diagnostic medical devices. • A certificate of free sale can be applied for by manufacturers or EU authorized representatives. • To apply for a certificate of free sale, the in vitro diagnostic medical devices must meet the legal requirements and be supported by a declaration of conformity. • Notified and CE-marked in vitro diagnostic medical devices are marketable within the EU and the associated contracting states, i.e. there is no need to issue a certificate. • The issuing of a certificate of free sale is subject to a

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	fee. • Responsible: State Office for the Environment (LfU) - Department 2 - Division 25.1
Ansprechpunkt	Please contact the State Office for the Environment (LfU) - Department 2 - Division 25.1.
Zuständige Stelle	
Formulare	Forms available: No Written form required: Yes Informal application possible: Yes Personal appearance necessary: No Online services available: Yes
Ursprungsportal	Freiverkaufszertifikate für aktive In-vitro Diagnostika beantragen, Apply for certificates of free sale for active in-vitro diagnostics