

99050178012001, 99050178012001

Apply for certificates of free sale for active medical devices

Heruntergeladen am 23.06.2025

<https://fimportal.de/xzufi-services/229676119/L100039>

Modul	Sachverhalt
Leistungsschlüssel	99050178012001, 99050178012001
Leistungsbezeichnung I	Apply for certificates of free sale for active medical devices
Leistungsbezeichnung II	Apply for certificates of free sale for active medical devices
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

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	und Export (2070200)
Einheitlicher Ansprechpartner	Ja
Fachlich freigegeben am	30.01.2023
Fachlich freigegeben 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://www.gesetze-im-internet.de/mpdg/ https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0745
Teaser	As a manufacturer of active medical devices or its authorized representative, you can apply for the issue of a certificate of free sale for export purposes. This certificate of free sale confirms the marketability of the products in question within the EU.
Volltext	Are you responsible for placing a medical device on the market and would like to export it outside the Union? Then the relevant competent authority will issue a certificate at 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 MDR
Voraussetzungen	• Your establishment is located in the area of responsibility of the relevant authority and you are registered in Eudamed. • 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

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	concerned is available.
Kosten	Gebühr: 100€ - 1.000€ https://landesrecht.rlp.de/bsrp/document/jlr-MPRKostVRPrahen
Verfahrensablauf	1. You submit your application. 2. The competent authority checks the documents. 3. The competent authority may request additional documents. additional documents. 4. If all requirements are met, the competent authority issues the certificate of free sale.
Bearbeitungsdauer	1 - 3 Woche(n)
Frist	There is no deadline for the application.
weiterführende Informationen	
Hinweise	
Rechtsbehelf	Objection according to Administrative Procedure Act (VwVfG) against the charging of fees
Kurztext	• Certificates of free sale for export purposes of medical devices Exhibition For medical devices excl. in vitro diagnostics - active • Certificates of free sale are issued for active 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 medical devices must meet the legal requirements and be supported by a declaration of conformity. • Medical devices that have been notified and CE-marked 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 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.

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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 Medizinprodukte beantragen, Apply for certificates of free sale for active medical devices