

99050178012003, 99050178012003

Applying for certificates of free sale for non-active medical devices

Heruntergeladen am 06.07.2025

<https://fimportal.de/xzufi-services/255616027/L100039>

Modul	Sachverhalt
Leistungsschlüssel	99050178012003, 99050178012003
Leistungsbezeichnung I	Applying for certificates of free sale for non-active medical devices
Leistungsbezeichnung II	Applying for certificates of free sale for non-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

Modul	Sachverhalt
	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 non-active medical devices or its authorized representative, you can apply for the issue of a certificate of free sale for export purposes outside the EU and countries that have a free trade agreement with the EU
Volltext	Are you responsible for placing a non-active medical device on the market and wish 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) of 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

Modul	Sachverhalt
	concerned is available. • It is a non-active medical device.
Kosten	Gebühr: 100€ - 1.000€ per free sale certificate for one country 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) The duration of processing depends on the time required to check the products.
Frist	There are no deadlines 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 the export of medical devices Issued for medical devices excluding in-vitro diagnostics - non-active • Certificates of free sale are issued for non-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 Social Affairs, Youth and

Modul	Sachverhalt
	Care (LSJV) - Department 5 - Division 54 - Medical Devices
Ansprechpunkt	Please contact the Landesamt für Soziales, Jugend und Versorgung (LSJV) - Abteilung 5 - Referat 54 - Medizinprodukte.
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 nicht-aktive Medizinprodukte beantragen, Applying for certificates of free sale for non-active medical devices