

99050178012004, 99050178012004

Applying for certificates of free sale for non-active in-vitro diagnostics

Heruntergeladen am 06.07.2025

<https://fimportal.de/xzufi-services/255616029/L100039>

Modul	Sachverhalt
Leistungsschlüssel	99050178012004, 99050178012004
Leistungsbezeichnung I	Applying for certificates of free sale for non-active in-vitro diagnostics
Leistungsbezeichnung II	Applying for certificates of free sale for non-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 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%3A32017R0746 https://www.gesetze-im-internet.de/mpdg/ https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0746
Teaser	As a manufacturer of non-active in-vitro diagnostics 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 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) 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 IVDR
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.

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	• Current documentation of the medical devices concerned is available. • It is a non-active in-vitro diagnostic device.
Kosten	Gebühr: 100€ - 1.000€ per free sale certificate for one country 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 requests additional documents if necessary. 4. If all requirements are met, the competent authority issues the certificate of free sale.
Bearbeitungsdauer	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 under the Administrative Procedure Act (VwVfG) against the charging of fees
Kurztext	• Certificates of free sale for export purposes of medical devices Issue for in vitro diagnostics - non-active • Certificates of free sale are issued for non-active in-vitro diagnostics. • 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. a certificate does not need to be issued. • The issuing of a certificate of free sale is subject to a fee.

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	• Responsible: State Office for Social Affairs, Youth and 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 In-vitro Diagnostika beantragen, Applying for certificates of free sale for non-active in-vitro diagnostics