

99050178012002, 99050178012002

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

Heruntergeladen am 10.07.2025

<https://fimportal.de/xzufi-services/386629415/L100001>

Modul	Sachverhalt
Leistungsschlüssel	99050178012002, 99050178012002
Leistungsbezeichnung I	Apply for certificates of free sale for active in-vitro diagnostics
Leistungsbezeichnung II	
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Hessen
Freigabestatus Katalog	unbestimmter Freigabestatus
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 und Export (2070200)

Modul	Sachverhalt
Einheitlicher Ansprechpartner	Ja
Fachlich freigegeben am	08.02.2023
Fachlich freigegeben durch	Hessian Ministry for Social Affairs and Integration (HMSI)
Handlungsgrundlage	https://www.gesetze-im-internet.de/mpdg/ https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0746 https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32017R0746 https://www.gesetze-im-internet.de/mpdg/ https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0746 https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32017R0746
Teaser	Are you responsible for placing an in-vitro diagnostic device on the market and would like to export it outside the Union? Then the competent authority will issue a certificate according to §10 MPDG upon your request.
Volltext	As a manufacturer of in-vitro diagnostics or its authorized representative, you can apply for the issue of a certificate of free sale for export purposes. The certificate of free sale confirms that the manufacturer or authorized representative has its registered place of business in Germany and that the product in question can be traded within the Union.
Erforderliche Unterlagen	• Declaration of conformity • Certificate(s) of the Notified Body(ies) • Product list
Voraussetzungen	• Product must be placed on the market in accordance with Article 5 Article 10 of Regulation (EU) 2017/746 of an in vitro diagnostic medical device • Only manufacturers and authorized representatives based in Germany can submit an application for a certificate of free sale for in vitro diagnostic medical devices here
Kosten	

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Verfahrensablauf	1. You submit your application 2. The competent authority checks the documents 3. The competent authority requests additional documents if necessary 4. The competent authority issues the certificate
Bearbeitungsdauer	1 - 3 Woche(n)
Frist	The certificate of marketability according to § 10 MPDG does not contain any time limits. It confirms the status as of the date of issue. Each recipient country decides on the period of validity of the certificate itself.
weiterführende Informationen	
Hinweise	
Rechtsbehelf	Appeal under the VwVfG against the rejection of an application and the charging of fees
Kurztext	• Certificates of free sale for export purposes for medical devices Exhibition For in-vitro diagnostics - active • Certificates of free sale are issued exclusively for medical devices and in-vitro diagnostics. • A certificate of free sale can only be applied for by the manufacturer or the European authorized representative based in the Federal Republic of Germany. • The medical devices and in-vitro diagnostics applied for must meet the legal requirements and be CE-marked. • CE-marked medical devices and in-vitro diagnostics can be marketed within the EU and the associated contracting states without official confirmation. This means that no certificate of free sale is issued. • Fee-based service
Ansprechpunkt	Please contact the Regierungspräsidium Kassel.
Zuständige Stelle	Regional Council Kassel
Formulare	Forms available: No Written form required: No Informal application possible: Yes Personal appearance necessary: No

Modul

Sachverhalt

Ursprungsportal

Freiverkaufszertifikate für aktive In-vitro Diagnostika
beantragen, Apply for certificates of free sale for active
in-vitro diagnostics