99050178012002, 99050178012002

Apply for a certificate of free sale for active in-vitro diagnostics

Modul	Sachverhalt
Leistungsschlüssel	99050178012002, 99050178012002
Leistungsbezeichnung I	Apply for a certificate of free sale for active in-vitro diagnostics
Leistungsbezeichnung II	
Typisierung	3a - Bundesaufsichtsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Mecklenburg-Vorpommern
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	

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Einheitlicher Ansprechpartner	Ja
Fachlich freigegeben am	15.03.2024
Fachlich freigegen durch	Mecklenburg-Vorpommern State Office for Health and Social Affairs
Handlungsgrundlage	https://www.gesetze-im-internet.de/mpdg/__10.html 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/__10.html https://www.landesrecht-mv.de/bsmv/document/jlr-MPKostVMVrahmen https://www.landesrecht-mv.de/bsmv/document/jlr-MPKostVMVrahmen
Teaser	Manufacturers of in-vitro diagnostics can apply for a certificate of free sale. 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.
Volltext	Are you responsible for placing an in vitro diagnostic medical device on the market in accordance with Article 5 and Article 10 of Regulation (EU) 2017/746 and wish to export it outside the Union? Then the relevant competent authority will issue a certificate in accordance with Section 10 MPDG at your request. This certificate certifies that the product may be traded in 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

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	certificate of free sale for in vitro diagnostic medical devices here
Kosten	Cost type: variable Description of costs: Fee Note: Medical device law is federal law and enforcement is the responsibility of the respective federal states. Therefore, the respective cost or fee regulations of the federal state must be applied.
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	Duration: 1 week to 3 weeks
Frist	Note (for further information on the time limit): 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 diagnostic medical devices applied for must meet the legal requirements and be CE-marked.

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	• 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	
Zuständige Stelle	
Formulare	
Ursprungsportal	Freiverkaufszertifikat für aktive In-vitro-Diagnostika beantragen, Apply for a certificate of free sale for active in-vitro diagnostics