99050178012004, 99050178012004

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

Modul	Sachverhalt
Leistungsschlüssel	99050178012004, 99050178012004
Leistungsbezeichnung I	Applying for certificates of free sale for non-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)

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Einheitlicher Ansprechpartner	Ja
Fachlich freigegeben am	08.02.2023
Fachlich freigegen durch	Hessian Ministry for Social Affairs and Integration (HMSI)
Handlungsgrundlage	• Medical Devices Implementation Act (MPDG) • Article 55 In-vitro Diagnostics Regulation (IVDR) - Regulation (EU) 2017/746 • Regulation (EU) 2017/746 Article 11 for EU authorized representatives 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 product on the market and would like to export it outside the Union? Then the relevant competent authority will issue a certificate upon your request.
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 would like 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

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	• 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	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	1 - 3 Woche(n) Duration: 1 to 3
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	Objection 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 - not 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

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	devices 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
Ursprungsportal	Freiverkaufszertifikate für nicht-aktive In-vitro Diagnostika beantragen, Applying for certificates of free sale for non-active in-vitro diagnostics