99050178012001, 99050178012001

Apply for certificates of free sale for active medical devices

Modul	Sachverhalt
Leistungsschlüssel	99050178012001, 99050178012001
Leistungsbezeichnung I	Apply for certificates of free sale for active medical devices
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 (HSMI)
Handlungsgrundlage	https://www.gesetze-im-internet.de/mpdg/ https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0745 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 https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0745
Teaser	Are you responsible for placing a medical device on the market and would like to export it outside the Union? Then the relevant competent authority will issue a certificate according to §10 MPDG upon your request.
Volltext	As a manufacturer of medical devices 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 and Article 10 of Regulation (EU) 2017/745 of a medical device • Only manufacturers and authorized representatives based in Germany can submit an application for a certificate of free sale for medical devices here
Kosten	
Verfahrensablauf	1. You submit your application

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	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 of medical devices Exhibition For medical devices excl. 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
Ursprungsportal	Freiverkaufszertifikate für aktive Medizinprodukte

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	beantragen, Apply for certificates of free sale for active medical devices