99050178012003, 99050178012003

Applying for certificates of free sale for non-active medical devices

Modul	Sachverhalt
Leistungsschlüssel	99050178012003, 99050178012003
Leistungsbezeichnung I	Applying for certificates of free sale for non-active medical devices
Leistungsbezeichnung II	
Typisierung	3a - Bundesaufsichtsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Mecklenburg-Vorpommern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
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%3A32017R0745 https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0745 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%3A32017R0745 https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0745
Teaser	Manufacturers of non-active medical devices can apply for a certificate of free sale. The certificate of free sale confirms that the manufacturer 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 a medical device on the market in accordance with Article 5 and Article 10 of Regulation (EU) 2017/745 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 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

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	certificate of free sale for 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	The certificate of marketability in accordance with § 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 the export of medical devices; issued for medical devices excluding in vitro diagnostic medical devices - not active • Certificates of free sale are issued exclusively for medical devices and in vitro diagnostic medical devices. • 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. • CE-marked medical devices and in vitro diagnostic medical devices can be marketed within the EU and the associated contracting states without official confirmation. This means that no certificate of free sale

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	is issued. • Fee-based service
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Freiverkaufszertifikate für nicht-aktive Medizinprodukte beantragen, Applying for certificates of free sale for non-active medical devices