99050178012000

Apply for certificates of free sale for medical devices

Modul	Sachverhalt
Leistungsschlüssel	99050178012000
Leistungsbezeichnung I	Apply for certificates of free sale for medical devices
Leistungsbezeichnung II	Apply for certificates of free sale for medical devices
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Baden-Württemberg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	

Modul	Sachverhalt
Fachlich freigegeben am	
Fachlich freigegen durch	
Handlungsgrundlage	Artikel 60 (EU) 2017/745 (MDR) Artikel 55 (EU) 2017/746 (IVDR) Medizinprodukterecht-Durchführungsgesetz (MPDG): • § 10 Freiverkaufszertifikate
Teaser	Are you responsible for placing a medical device on the market in accordance with Article 5 of Regulation (EU) 2017/745 on medical devices or Regulation (EU) 2017/746 on in vitro diagnostic medical devices and would like to export this to non-EU third countries ? Then the relevant competent authority can issue a certificate in accordance with Section 10 MPDG at your request.
Volltext	Are you responsible for placing a medical device on the market in accordance with Article 5 of Regulation (EU) 2017/745 on medical devices or Regulation (EU) 2017/746 on in vitro diagnostic medical devices and would like to export this to non-EU third countries ? Then the relevant competent authority can issue a certificate in accordance with Section 10 MPDG at your request. This certificate certifies that the product may be traded in the EU.
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 or 11 of Regulation (EU) 2017/745 of a medical device • Product must be placed on the market in accordance with Article 5 and Article 10 or 11 of Regulation (EU) 2017/746 of an in vitro diagnostic medical device • Only manufacturers and authorised representatives based in Germany can submit an application for a certificate of free sale for medical devices and in vitro

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	diagnostic medical devices here
Kosten	Cost type: variable Description of costs: Fee Note: Medical device law is federal law and is enforced by the respective federal states. Therefore, the respective fee ordinance 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: up to 3 weeks
Frist	The certificate of marketability according to § 10 MPDG 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	The online service is still under construction, please contact the responsible regional council.
Rechtsbehelf	• Appeal under the LVwVfG against the rejection of an application and the charging of fees
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	