99050178012000

Free sale certificates for export purposes of medical devices issuance

Modul	Sachverhalt
Leistungsschlüssel	99050178012000
Leistungsbezeichnung I	Free sale certificates for export purposes of medical devices issuance
Leistungsbezeichnung II	Apply for free sale certificates for medical devices
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	Export certificate , certification , MDR , Export certificates for medical devices , Marketability of medical devices , Export of medical products , FSC , <div

Modul	Sachverhalt
	lang="en-x-mtfrom-de">Free Sales Certificate , Free Sale Certificate , Certificate § 10 MPDG , apostille , legalization , IVDR
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	21.07.2023
Fachlich freigegen durch	
Handlungsgrundlage	§ 10 Medical Devices Law Implementation Act Article 60 Regulation (EU) 2017/745 (MDR) Article 55 Regulation (EU) 2017/746 (MDR)
Teaser	As a manufacturer of medical devices and in-vitro diagnostics or its authorized representative, you can apply for the issuance of a free sale certificate for export purposes.
Volltext	Are you responsible for placing a medical device on the market according to Article 5 and Article 10 of Regulation (EU) 2017/745 or Article 5 and Article 10 of Regulation (EU) 2017/746 of an in-vitro diagnostic device and would like to export it outside the Union? Then the competent authority will issue a certificate according to § 10 MPDG upon your application. This certificate certifies that the product can be traded in the Union.
Erforderliche Unterlagen	Declaration of Conformity(s) Certificate(s) from the notified body(s) product list

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Voraussetzungen	The product must be placed on the market according to Article 5 and Article 10 of Regulation (EU) 2017/745 for a medical device or Article 5 and Article 10 of Regulation (EU) 2017/746 for an in-vitro diagnostic device Only manufacturers and authorized representatives based in Hamburg can apply for a free sale certificate for medical devices or in-vitro diagnostics here
Kosten	Medical product law is federal law and is enforced under the sovereignty of the respective federal states. Therefore, the respective cost or fee schedule of the federal state must be applied. In the Free and Hanseatic City of Hamburg, this is the schedule of fees for public consumer protection.
Verfahrensablauf	You submit your application The competent authority checks the documents The competent authority may request additional documents The competent authority issues the certificate
Bearbeitungsdauer	1 to 3 weeks
Frist	The certificate of marketability according to § 10 MPDG does not contain any limitations. It confirms the status as of the date of issue. Each recipient country decides for itself how long the certificate is valid.
weiterführende Informationen	
Hinweise	No
Rechtsbehelf	Objection according to VwVfG against rejection of an application or the charging of fees
Kurztext	Free sale certificates are only issued for medical devices and in-vitro diagnostics. A free sale certificate 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. Within the EU and the associated contracting states, CE-marked medical products can be marketed without official confirmation. Ie no free sale certificate will be issued.

Modul	Sachverhalt
	Paid service
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority
Formulare	
Ursprungsportal	Hamburg Service, Hamburg Service (Currently this link is only available in german)