

99050178012000, 99050178012001, 99050178012002,
 99050178012003, 99050178012004

Heruntergeladen am 07.07.2025

<https://fimportal.de/xzufi-services/55047/L100042>

Modul	Sachverhalt
Leistungsschlüssel	99050178012000, 99050178012001, 99050178012002, 99050178012003, 99050178012004
Leistungsbezeichnung I	
Leistungsbezeichnung II	Medical devices; application for a certificate of free sale
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Bayern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	

Modul	Sachverhalt
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	04.12.2024
Fachlich freigegeben durch	Bayerisches Staatsministerium für Gesundheit, Pflege und Prävention (Bavarian State Ministry of Health, Care and Prevention)
Handlungsgrundlage	https://www.gesetze-bayern.de/Content/Document/BayZustVGA-ANL_1 https://www.gesetze-bayern.de/Content/Document/BayZustVGA-ANL_1 http://www.gesetze-im-internet.de/mpdg/_10.html http://www.gesetze-im-internet.de/mpdg/_10.html 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://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32017R0746 https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32017R0746 https://www.gesetze-bayern.de/Content/Document/BayKVzKG-ANL_1 https://www.gesetze-bayern.de/Content/Document/BayKVzKG-ANL_1
Teaser	For the export of a medical device, manufacturers can apply for a certificate of marketability of the medical device in Germany (certificate of free sale).
Volltext	Some third countries require proof that the medical device in question is marketable in the European Economic Area (EEA) before it can be placed on the market in their country. The certificate of marketability issued by the competent authority (certificate of free sale) serves as this proof. Competent authorities The Bavarian State Office for Health and Food Safety (LGL) is responsible for active medical devices. The following governments are responsible for

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	non-active medical devices: • Government of Upper Franconia: responsible for the administrative districts of Upper Palatinate, Upper Franconia, Middle Franconia and Lower Franconia • Government of Upper Bavaria: responsible for the administrative districts of Lower Bavaria, Upper Bavaria and Swabia.
Erforderliche Unterlagen	• Proof of the marketability of the medical devices to be exported (declarations of conformity, certificates from a notified body) If there are several products, it makes sense to enclose a summary in the form of a text or table file.
Voraussetzungen	The requirements are set out in Section 10 of the Medical Devices Law Implementation Act (MPDG). At the request of the manufacturer or its authorized representative, the competent authority shall issue a certificate of free sale in accordance with Article 60(1) of Regulation (EU) 2017/745 or Article 55(1) of Regulation (EU) 2017/746 (IVDR). A certificate of free sale may also be issued for devices placed on the market in accordance with Article 120(3) of Regulation (EU) 2017/745 or Article 110(3) of Regulation (EU) 2017/746. This applies accordingly to devices that were lawfully placed on the market before May 26, 2021 in accordance with the national provisions transposing Directives 90/385/EEC and 93/42/EEC and may continue to be made available on the market or put into service until May 26, 2025.
Kosten	The fee is set out in the schedule of costs, tariff no. 7.I.9/6. The costs (fee and expenses) are to be borne by the applicant.
Verfahrensablauf	The certificate of free sale must be applied for from the competent authority: • for active medical devices: to the Bavarian State Office for Health and Food Safety • for non-active medical devices: depending on the manufacturer's place of business, to the Government of Upper Franconia or the Government of Upper Bavaria

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	The application can be submitted online using the online procedure provided.
Bearbeitungsdauer	The processing time depends on the scope of the documents to be checked.
Frist	Deadlines do not have to be observed.
weiterführende Informationen	
Hinweise	
Rechtsbehelf	Administrative court action
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal