

99050178012000, 99050178012000

Medical devices - certificate of marketability

Heruntergeladen am 10.07.2025

<https://fimportal.de/xzufi-services/209236431/L100038>

Modul	Sachverhalt
Leistungsschlüssel	99050178012000, 99050178012000
Leistungsbezeichnung I	Medical devices - certificate of marketability
Leistungsbezeichnung II	
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Thüringen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Gewerbe (050)
Verrichtungskennung	Ausstellung (012)
SDG-Informationsbereich	
Lagen Portalverbund	Import und Export (2070200), Erlaubnisse und Genehmigungen (2010400)
Einheitlicher	

Modul	Sachverhalt
Ansprechpartner	Nein
Fachlich freigegeben am	24.08.2017
Fachlich freigegeben durch	Thuringian Ministry of Labor, Social Affairs, Health, Women and Family (TMASGFF)
Handlungsgrundlage	https://www.gesetze-im-internet.de/mpg/ http://www.landesrecht-thueringen.de/jportal/?quelle=jlink&query=SozMinVwKostO+TH&psml=bsthueprod.psml&max=true https://www.gesetze-im-internet.de/mpg/ http://www.landesrecht-thueringen.de/jportal/?quelle=jlink&query=SozMinVwKostO+TH&psml=bsthueprod.psml&max=true
Teaser	If you want to place medical devices on the market for the first time, you can apply for a certificate of marketability of the medical device(s) for export.
Volltext	Manufacturers or authorized representatives placing medical devices on the market for the first time may apply for a certificate of marketability of the medical device(s) for export.
Erforderliche Unterlagen	The manufacturer's current declaration(s) of conformity for the medical devices and the certificate from the Notified Body (except for Class I devices), if these have not already been submitted.
Voraussetzungen	The manufacturer or authorized representative must be based in Thuringia and the medical devices to be exported must be indicated in the DIMDI Information System Medical Devices.
Kosten	Fees are charged in accordance with the Thuringian Administrative Cost Regulations for the Ministry of Labor, Social Affairs, Health, Women and Family Affairs (TMASGFF); Part E; No. 2.1.4. The amount of the fees (80.00 to 500.00 Euro) is differentiated between a first-time issuance and the issuance of a further marketability certificate as well as the number of contained products.
Verfahrensablauf	The application can be submitted informally by e-mail

Modul	Sachverhalt
	or by mail. In addition to the applicant's contact details, the application should contain the following information: • the exact designations of all medical devices to be exported (if applicable, with article numbers and/or other additions required for identification) • the indication of the country of destination (if this is to be indicated) • the language accepted in the country of destination (recipient country) (English, Spanish or French) • if applicable, the number of similar certificates of marketability to be issued (in case of certificates without indication of a country of destination)
Bearbeitungsdauer	
Frist	
weiterführende Informationen	
Hinweise	
Rechtsbehelf	
Kurztext	• Medical devices - certificate of marketability • Manufacturers or authorized representatives who place medical devices on the market for the first time can apply for a certificate of marketability of the medical device(s) for export. • The application can be made informally by email or by mail. • Fees will apply. • Responsible: Thuringian State Office for Consumer Protection (TLV); Department 21 - Technical Consumer Protection, Market Surveillance.
Ansprechpunkt	Contact the Thuringian State Office for Consumer Protection (TLV); Department 21 - Technical Consumer Protection, Market Surveillance.
Zuständige Stelle	
Formulare	informal application

Modul

Sachverhalt

Ursprungsportal

Medizinprodukte - Bescheinigung über die
Verkehrsfähigkeit, Medical devices - certificate of
marketability