99050178012002

Apply for certificates of free sale for active in-vitro diagnostics

Modul	Sachverhalt
Leistungsschlüssel	99050178012002
Leistungsbezeichnung I	Apply for certificates of free sale for active in-vitro diagnostics
Leistungsbezeichnung II	Apply for certificates of free sale for active in-vitro diagnostics
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Nordrhein-Westfalen
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	fachlich freigegeben (silber)
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	Erlaubnisse und Genehmigungen (2010400), Import

Modul	Sachverhalt
	und Export (2070200)
Einheitlicher Ansprechpartner	Ja
Fachlich freigegeben am	02.11.2023
Fachlich freigegen durch	Ministry of Labor, Health and Social Affairs of the State of North Rhine-Westphalia
Handlungsgrundlage	Medical Devices Implementation Act (MPDG) Article 55 In-vitro Diagnostics Regulation (IVDR) - Regulation (EU) 2017/746 Regulation (EU) 2017/746 Article 11 for EU authorized representatives https://www.gesetze-im-internet.de/mpdg/ https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0746 https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32017R0746 https://www.gesetze-im-internet.de/mpdg/ https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0746 https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32017R0746
Teaser	As a manufacturer of in-vitro diagnostics or its authorized representative, you can apply for the issue of a certificate of free sale for export purposes. The certificate of free sale confirms that the manufacturer or authorized representative 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 an in vitro diagnostic medical device on the market in accordance with Article 5 and Article 10 of Regulation (EU) 2017/746 and would like 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.

Modul	Sachverhalt
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 Article 10 of Regulation (EU) 2017/746 of an in vitro diagnostic medical device • Only manufacturers and authorized representatives based in Germany can submit an application for a certificate of free sale for in vitro diagnostic medical devices here
Kosten	The costs are based on the General Administrative Fee Regulations for the State of North Rhine-Westphalia (Allgemeine Verwaltungsgebührenordnung NRW - AVwGebO NRW). Tariff item 12.1.6.3.9.
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	If the documents are complete, your application will be processed promptly.
Frist	The certificate of marketability according to § 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	Appeal under the VwVfG against the rejection of an application and the charging of fees
Kurztext	• Certificates of free sale for export purposes for medical devices Exhibition For in-vitro diagnostics - active • Certificates of free sale are issued exclusively for medical devices and in-vitro diagnostics. • A certificate of free sale can only be applied for by the manufacturer or the European authorized

Modul	Sachverhalt
	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. • CE-marked medical devices and in-vitro diagnostics can be marketed within the EU and the associated contracting states without official confirmation. This means that no certificate of free sale is issued. • Fee-based service
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Freiverkaufszertifikate für aktive In-vitro Diagnostika beantragen, Apply for certificates of free sale for active in-vitro diagnostics