

99005105012000, 99005105012002, 99005105012001

Heruntergeladen am 26.06.2025

<https://fimportal.de/xzufi-services/12136/L100042>

Modul	Sachverhalt
Leistungsschlüssel	99005105012000, 99005105012002, 99005105012001
Leistungsbezeichnung I	
Leistungsbezeichnung II	Medicinal products; application for a WHO certificate for export
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Bayern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	27.05.2025

Modul	Sachverhalt
Fachlich freigegeben durch	Bayerisches Staatsministerium für Gesundheit, Pflege und Prävention (Bavarian State Ministry of Health, Care and Prevention)
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/_73a.html https://www.gesetze-im-internet.de/amg_1976/_73a.html https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=celex:32019R0006&from=it https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=celex:32019R0006&from=it https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB https://www.gesetze-bayern.de/Content/Document/BayKVzKG-ANL_1 https://www.gesetze-bayern.de/Content/Document/BayKVzKG-ANL_1
Teaser	A certificate in accordance with the World Health Organization's certificate system must be applied for in order to export medicinal products.
Volltext	At the request of the pharmaceutical entrepreneur, the manufacturer, the exporter or the competent authority of the country of destination, the competent authorities shall issue a certificate for the export of medicinal products in accordance with the certificate system of the World Health Organization (WHO) pursuant to Section 73 a (2) of the German Medicinal Products Act (AMG). Responsibilities The governments of Upper Bavaria and Upper Franconia are responsible for issuing the export certificate. The government of Upper Bavaria is responsible for the administrative districts of Lower Bavaria, Upper Bavaria and Swabia, while the government of Upper Franconia is responsible for the administrative districts of Middle Franconia, Upper Franconia, Lower

Modul	Sachverhalt
	Franconia and Upper Palatinate.
Erforderliche Unterlagen	• List of medicines to be administered according to the WHO scheme • Country of destination • Complete composition of the dosage form, if applicable • If applicable, the approved instructions for use/technical information • List of manufacturers, if applicable • If an authorized representative applies for the certificate, declaration of consent from the approval holder
Voraussetzungen	An authority in the country of destination requires an export certificate.
Kosten	Cost per preparation: EUR 50 (according to cost schedule - tariff no. 7.IX.8 / tariff item 8.1)
Verfahrensablauf	If an export certificate (certificate of origin) is required by the authorities of the country of destination for the export of medicinal products, you as a pharmaceutical company can apply for it from the competent authorities.
Bearbeitungsdauer	
Frist	Deadlines do not have to be observed.
weiterführende Informationen	
Hinweise	
Rechtsbehelf	Administrative court action
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal