

99005105012000, 99005105012002, 99005105012001

Heruntergeladen am 16.06.2025

<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         | <a href="https://www.gesetze-im-internet.de/amg_1976/_73a.html">https://www.gesetze-im-internet.de/amg_1976/_73a.html</a><br><a href="https://www.gesetze-im-internet.de/amg_1976/_73a.html">https://www.gesetze-im-internet.de/amg_1976/_73a.html</a><br><a href="https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=celex:32019R0006&amp;from=it">https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=celex:32019R0006&amp;from=it</a><br><a href="https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=celex:32019R0006&amp;from=it">https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=celex:32019R0006&amp;from=it</a><br><a href="https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB">https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB</a><br><a href="https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB">https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB</a><br><a href="https://www.gesetze-bayern.de/Content/Document/BayKVzKG-ANL_1">https://www.gesetze-bayern.de/Content/Document/BayKVzKG-ANL_1</a><br><a href="https://www.gesetze-bayern.de/Content/Document/BayKVzKG-ANL_1">https://www.gesetze-bayern.de/Content/Document/BayKVzKG-ANL_1</a> |
| Teaser                     | A certificate in accordance with the World Health Organization's certificate system must be applied for in order to export medicinal products.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Volltext                   | <p>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).</p> <p><b>**Responsibilities**</b></p> <p>The governments of Upper Bavaria and Upper Franconia are responsible for issuing the export certificate.</p> <p>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</p>                                                                                                                                                                                                                                                                                                                                                                                              |

| Modul                        | Sachverhalt                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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|                              | Franconia and Upper Palatinate.                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Erforderliche Unterlagen     | <ul style="list-style-type: none"> <li>• List of medicines to be administered according to the WHO scheme</li> <li>• Country of destination</li> <li>• Complete composition of the dosage form, if applicable</li> <li>• If applicable, the approved instructions for use/technical information</li> <li>• List of manufacturers, if applicable</li> <li>• If an authorized representative applies for the certificate, declaration of consent from the approval holder</li> </ul> |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                         |