99005008005000, 99005008005000

# Apply for a certificate for a pharmaceutical product for the export of medicinal products for human use



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| **Leistungsschlüssel** | 99005008005000, 99005008005000 |
| **Leistungsbezeichnung I** | Apply for a certificate for a pharmaceutical product for the export of medicinal products for human use |
| **Leistungsbezeichnung II** | |
| **Typisierung** | 3a - Bundesaufsichtsverwaltung: Regelung, Land: Vollzug |
| **Quellredaktion** | Mecklenburg-Vorpommern |
| **Freigabestatus Katalog** | unbestimmter Freigabestatus |
| **Freigabestatus Bibliothek** | unbestimmter Freigabestatus |
| **Begriffe im Kontext** | |
| **Leistungstyp** | Leistungsobjekt mit Verrichtung |
| **Leistungsgruppierung** | Arzneimittel (005) |

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| **Verrichtungskennung** | Erlaubnis (005) |
| **SDG-Informationsbereich** | Zollverfahren für Einfuhren und Ausfuhren gemäß dem Zollkodex der Union |
| **Lagen Portalverbund** | |
| **Einheitlicher Ansprechpartner** | Nein |
| **Fachlich freigegeben am** | 28.02.2023 |
| **Fachlich freigegen durch** | Ministry of Social Affairs, Health and Sports Mecklenburg-Western Pomerania |
| **Handlungsgrundlage** | https://www.gesetze-im-internet.de/amg_1976/__72.html<br>https://www.gesetze-im-internet.de/amg_1976/__73a.html<br>https://www.landesrecht-mv.de/bsmv/document/jlr-GesKostVMVV5Anlage |
| **Teaser** | For the export of a human medicinal product approved in Germany to a country outside the EU, you need the WHO certificate, which is issued according to the specifications of the World Health Organization (WHO). |
| **Volltext** | Germany participates in the "World Health Organization (WHO) Certificate System on the Quality of Pharmaceutical Products in International Trade". Certificates under this system attest to the marketability of the human drug in the country of origin and serve to facilitate the movement of pharmaceutical products.<br><br>In principle, the certificates are issued by the competent authority of the federal state in which the medicinal product is manufactured and authorized (exporting country).<br><br>For medicinal products manufactured outside Germany, only approval-related information can be certified. In this case, the certification of the GMP information (GMP - Good Manufacturing Practice) takes place in the country of manufacture. The WHO certificate with GMP information certifies that the |

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| | medicinal product complies with the "WHO Basic Rules for the Manufacture of Medicinal Products and Quality Assurance".<br><br>If it is a question of confirming marketing authorization-related information and the marketing authorization holder is based outside Germany, the higher federal authorities are responsible for issuing the WHO certificate.<br><br>A WHO certificate can serve the competent authorities of importing third countries in the following regulatory situations:<br><br>• in the context of applications for marketing authorization<br>• in the context of applications for renewal, extension, amendment or review of a marketing authorization<br>• in the context of imports of medicinal products authorized in the exporting country.<br><br>WHO certificates can be applied for by the marketing authorization holder (pharmaceutical entrepreneur), by the manufacturer, by the exporter of the medicinal product authorized in Germany or by the competent authority of the country of destination. For this purpose, you have to submit all documents required for the decision on the issuance of the WHO certificate.<br><br>Before a WHO certificate is issued, the certifying authority checks the information for correctness and completeness. |
| **Erforderliche Unterlagen** | • The WHO Certificate for Pharmaceutical Products (CPP) prepared in terms of content.<br>• Declaration that no change has been made outside the designated fields in the deposited form (only in the case of a paper-based application)<br>• If applicable, the directions for use/specialty information approved by the relevant national regulatory authority<br>• Complete composition of the dosage form, if applicable |

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| | • if applicable, summary of the basis for the marketing authorization<br>• if an authorized representative is applying for the certificate, a declaration of the approval of the marketing authorization holder (power of attorney) |
| **Voraussetzungen** | • You must be the marketing authorization holder, manufacturer or a person or authority of the country of destination authorized by the marketing authorization holder.<br>• If you are not the marketing authorization holder, the permission of the marketing authorization holder/authorized representative is required. |
| **Kosten** | Fee range: 60 - 15,000 euros. Additional costs arise depending on the type of any additional certification requested. |
| **Verfahrensablauf** | • You have the option of submitting the application via the online form or in writing.<br>• If you submit the application via the online form, submit the completed online form and the required attachments to the competent authority.<br>• In case of paper-based application, send the completed WHO draft with the required documents to the competent authority by mail and, if necessary, additionally by e-mail.<br>• The application and documents will be checked for accuracy and completeness. If the legal requirements are met and all information is correct and up-to-date, the WHO certificate will be issued.<br>• If you have additionally applied for over-certification, the requested over-certification will be carried out by the competent ministry.<br>• You will receive the requested certificate and the fee notice by mail.<br>• Payment is made in arrears (bank transfer after receipt of the fee notice).<br><br>**Additional information:**<br><br>• The applicant shall submit all documents and information relevant to the decision on issuance of the |

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| | WHO certificate.<br>• In cases where an authorized person applies for a WHO certificate, the consent of the marketing authorization holder is required. A written authorization to this effect must be submitted.<br>• The specifications of the WHO model must be adhered to. Non-relevant passages in the text must not be omitted, i.e. empty fields for sections on which no statement can or should be made remain blank. Additions serving transparency (e.g. trade name in the recipient country) may be included in an annex if necessary.<br>• Annexes belonging to the certificate must be attached in a neutral form (without company logo; does not apply to samples, e.g. the directions for use) and at least in German. Another official WHO language (English, French, Spanish) may be considered.<br>• The required forms are linked below. The certifying authority must be satisfied that the information is correct and up to date.<br>• The official language is German. The foreign language part (according to the official WHO translation) of the synoptic certificate is neither signed nor sealed/stamped by the authority.<br>• The issuance of a synoptic certificate in a language for which the WHO does not provide an official translation is possible upon presentation of a translation by a state-recognized translator whose signature must be notarized. The "General Notes" and "Explanatory Notes" are an integral part of each certificate and must always be enclosed. Please also refer to the explanations of the individual numbers in the appendix of the WHO certificate as well as the WHO guidelines.<br>• The declaration of the approval status for (a) pharmaceutical product(s) is not subject of this application procedure. Batch certificates for pharmaceutical products are not subject of this application procedure.<br>• Such a certificate is applied for by the manufacturer and is only issued by the higher federal authority conducting the batch testing, the Paul Ehrlich Institute (PEI), if governmental batch tests are prescribed and conducted for the product.<br>https://www.zlg.de/arzneimittel/service/dokumente |

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| | https://www.zlg.de/index.php?eID=dumpFile&t=f&f=2683&token=323c0f030c86783d3255314593efe54c88b51c10<br>https://www.zlg.de/index.php?eID=dumpFile&t=f&f=2682&token=8d9fe56eee586d64d4072d88430d5c143f21c2ad<br>https://www.auswaertiges-amt.de/de/service/fragenkatalog-node/12-apostille-ausl/606196<br>https://www.zlg.de/arzneimittel/service/dokumente<br>https://www.zlg.de/index.php?eID=dumpFile&t=f&f=2683&token=323c0f030c86783d3255314593efe54c88b51c10<br>https://www.zlg.de/index.php?eID=dumpFile&t=f&f=2682&token=8d9fe56eee586d64d4072d88430d5c143f21c2ad<br>https://www.auswaertiges-amt.de/de/service/fragenkatalog-node/12-apostille-ausl/606196 |
| **Bearbeitungsdauer** | 3 Monat(e)<br>As soon as the required documents are complete and correct, the certificate is usually issued within 2 to 4 weeks after application. If special over-certifications have been requested, their processing time is not included.<br>3 Monat(e)<br>As soon as the required documents are complete and correct, the certificate will be issued. the certificate is usually issued within 2 to 4 weeks of the application being submitted. If special over-certifications have been requested, their processing time is not included. processing time is not included. |
| **Frist** | |
| **weiterführende Informationen** | |
| **Hinweise** | |
| **Rechtsbehelf** | An appeal against this decision may be lodged with the competent administrative court (depending on the registered office of the licensee or applicant) within one month of notification. |
| **Kurztext** | • WHO Certificate (CPP) for the export of medicinal products for human use Issue. |

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| | • Application for issuance of a certificate according to the World Health Organization (WHO) certificate system.<br>• It may be necessary for the export (export) of a medicinal product or for marketing authorization purposes in a third country.<br>• Application procedure online or in writing<br>• Responsibility: State Office for Health and Social Affairs (LAGuS) |
| **Ansprechpunkt** | |
| **Zuständige Stelle** | LAGuS M-V |
| **Formulare** | • Forms available: Yes<br>• Written form required: No<br>• Informal application possible: No<br>• Personal appearance required: No |
| **Ursprungsportal** | Apply for a certificate for a pharmaceutical product for the export of medicinal products for human use, Zertifikat für ein pharmazeutisches Produkt für die Ausfuhr von Humanarzneimitteln beantragen |