



99003086001000

Export license for narcotics Issue

Heruntergeladen am 16.06.2025 https://fimportal.de/xzufi-services/106189814/B100019

Modul	Sachverhalt
Leistungsschlüssel	99003086001000
Leistungsbezeichnung I	Export license for narcotics Issue
Leistungsbezeichnung II	Applying for an export license for narcotics
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Erteilung (1)
SDG-Informationsbereich	nicht SDG-relevant
Lagen Portalverbund	Import und Export (2070200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	01.04.2025





Modul	Sachverhalt
Fachlich freigegen durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://www.gesetze-im-internet.de/btmg_1981/11.ht ml https://www.gesetze-im-internet.de/btmahv/BJNR0142 00981.html https://www.gesetze-im-internet.de/bmgbgebv/anlage. html
Teaser	If you wish to export narcotics from Germany, you must apply for an export license from the Federal Institute for Drugs and Medical Devices (BfArM). Under certain circumstances, you can apply for a clearance certificate instead.
Volltext	In order to apply for an export permit, you need a permit to handle narcotics. The permit is valid for a maximum of 3 months. After you have exported the narcotics, you must immediately inform the Federal Institute for Drugs and Medical Devices (BfArM) of the process in an export notification. If you do not export the narcotics within the period specified in the export license, you must also report this in an export notification immediately after the period has expired. If the substance or preparation in question is not subject to narcotics legislation in Germany, you may require a clearance certificate as a substitute for the export license. This clearance certificate officially certifies that a substance or preparation is not subject to narcotics legislation in Germany. The application procedure for clearance certificates is primarily aimed at companies, in particular from the pharmaceutical sector, which trade in medicinal products or active substances across borders on the basis of pharmaceutical legislation. You can also use the application procedure if you • are a scientific institution or
	 are a scientific institution or a company that supplies scientific institutions with reference solutions.





Modul Sachverhalt

The clearance certificate is intended exclusively for submission to the foreign authority responsible for narcotics traffic. It serves as a substitute for an export license in accordance with the Narcotics Act (BtMG) and the Narcotics Foreign Trade Ordinance (BtMAHV).

The Federal Opium Agency at the Federal Institute for Drugs and Medical Devices (BfArM) is responsible for the export license and the clearance certificate.

Erforderliche Unterlagen

For export license:

- Narcotics (BtM) number
- Permit for handling narcotics
- Import permit of the importing country

For clearance certificate:

- chemical structural formula, including molecular formula and molecular weight of the substance or the substance in the preparation
- Chemical name according to the "International Non-proprietary Name of the World Health Organization" (INN) or the "International Union of Pure and Applied Chemistry" (IUPAC)
- Chemical Abstracts Service (CAS) number, if available
- Details of the country to which the export is to be made
- If applying as an organization without an existing permit to handle narcotics: Header sheet of the organization with:
 - Details of the commercial register number or
 - BtM number

Voraussetzungen

- You are based in Germany or the applicant organization is based in Germany.
- You or the applicant organization have a permit to handle narcotics in order to participate in narcotics traffic.
- You or the applicant organization have the corresponding import permit from the importing





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country.

- For a clearance certificate, it is necessary that you
- are an organization or a company based in Germany that regularly trades in medicinal products or active substances on the basis of the German Medicinal Products Act or
- are a scientific institution or a company that regularly supplies scientific institutions with reference solutions or other chemicals for scientific purposes.

Kosten

Gebühr: 70€ - 350€

https://www.gesetze-im-internet.de/bmgbgebv/anlage.

html

Verfahrensablauf

You can apply for the export license in writing by post:

- Fill out the export license application form.
- Print out the application form so that the front and back are on one sheet, sign it and send it together with all the necessary documents by post to the Federal Institute for Drugs and Medical Devices (BfArM).
 - The BfArM will check your details and documents.
- The BfArM will notify you if you need to submit additional information or documents.
- If you are granted the export license, the BfArM will send you the export license in duplicate and a notification of fees by post. Pay the fees within 30 days.

You can apply for the clearance certificate online, by post or fax from the BfArM.

If you apply for the clearance certificate online:

- Go to the website of the federal portal and access the online application. This will guide you step by step through the necessary information, which you can enter electronically.
- You will need an ELSTER business account and an ELSTER certificate to submit the application.
- Upload the required documents as a file and send the application. The file must not be larger than 10 megabytes. The following formats are accepted:
 - PDF





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- PNG
- JPEG
- The BfArM will check your information and documents.
- The BfArM will notify you if you need to submit additional information or documents.
- You will receive the clearance certificate and a notification of costs by post. Pay the fees within 30 days.

If you apply for a clearance certificate by post or fax:

- Compose an informal written application on the headed paper of your institution including commercial register number with details of
 - · Your organization,
 - · your BtM number, if available, and
 - · detailed information on the substance and
 - detailed information on the country of export
- Send the letter and all required documents to the BfArM by post or fax.
- The BfArM will check your information and
- The BfArM will notify you if you need to submit additional information or documents.
- You will receive the clearance certificate and a notification of costs by post. Pay the fees within 30 days.

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Bearbeitungsdauer	5 - 7 Werktag(e)
Frist	1 - 3 Monat(e) 1 Jahr(e)
weiterführende Informationen	https://www.bfarm.de/DE/Bundesopiumstelle/Betaeub ungsmittel/Einfuhr-und-Ausfuhr/_node.html https://www.bfarm.de/DE/Bundesopiumstelle/_FAQ/Be taeubungsmittel/Ausfuhr/faq-liste.html
Hinweise	There are no indications or special features
Rechtsbehelf	 Contradiction Detailed information on how to lodge an objection can be found in the notification.





Modul	Sachverhalt
	Administrative court action
Kurztext	 an export license is required for the export of narcotics from Germany In addition, a permit to handle narcotics (BtM permit) is required After export, export notification is mandatory and immediate Export license valid for a maximum of 3 months Alternatively, if required: application for a clearance certificate for substances or preparations that are not subject to narcotics legislation in Germany Clearance certificate serves as a substitute for an export license under the Narcotics Act (BtMG) and the Narcotics Foreign Trade Ordinance (BtMAHV) for submission to the foreign authority responsible for narcotics traffic Clearance certificate valid for 1 year in each case
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Ausfuhrgenehmigung Betäubungsmittel Erteilung, Export license for narcotics Issue