

99005006005000

Import of tissue permit

Heruntergeladen am 19.06.2025

<https://fimportal.de/xzufi-services/S1000020010000012022/S100002>

Modul	Sachverhalt
Leistungsschlüssel	99005006005000
Leistungsbezeichnung I	Import of tissue permit
Leistungsbezeichnung II	Permission to import tissue
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	<div lang="en-x-mtfrom-de">Tissues and tissue preparations</div>, <div lang="en-x-mtfrom-de">import permit</div>, <div lang="en-x-mtfrom-de">Permission requirement</div>
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	

Modul	Sachverhalt
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	12.08.2022
Fachlich freigegeben durch	
Handlungsgrundlage	
Teaser	You need a permit to import tissue or tissue preparations from a third country.
Volltext	In order to import tissue within the meaning of the Transplantation Act or tissue preparations within the meaning of the Medicines Act into Germany, you must apply for a permit
Erforderliche Unterlagen	• Permission according to § 20c AMG of the tissue establishment • Job description of the responsible person and information sheet "Appointment/appointment of a representative or change of the responsible person in accordance with Section 20c Paragraph 2 No. 1 AMG or Section 72b AMG" • Information on the relevant qualifications and training of the responsible person • Police clearance certificate of type O • Copy of the original label, the outer packaging label and the documentation for the outer packaging and the transport container • List of relevant, current standard operating procedures (SOPs) for the facility's import activities • SOP for the application of the Single European Code, the reception and storage of imported tissues and cells in the importing tissue establishment • Management of serious incidents and serious adverse reactions • Management of recalls and traceability from donor to recipient
Voraussetzungen	• You are a commercial tissue establishment and have a licence to process, preserve, test, store or place tissue or tissue preparations on the market. • They have the appropriate knowledgeable and reliable staff. • You have a contract with a third-country institution.

Modul	Sachverhalt
	• They have a quality management system for handling imports (SOP's). • The imported preparations are provided with origin and outer packaging labels.
Kosten	Fees apply. The amount of the fees depends on the time required for processing. They are calculated based on the state fee schedule.
Verfahrensablauf	• You submit your written application for an import permit and all necessary documents to the competent authority. • The responsible authority will examine your application and your documents and, if necessary, request further documents from you. • The responsible authority will decide on your application. • You will receive notification of the decision.
Bearbeitungsdauer	Processing takes 4 to 6 weeks.
Frist	The application should be submitted at least six weeks before the planned import of tissue or tissue preparations.
weiterführende Informationen	https://www.hamburg.de/politik-und-verwaltung/behoerden/bjv/themen/verbraucherschutz/pharmaziewesen/gewebe-89008 https://www.hamburg.de/pharmaziewesen/124680/gewebe/
Hinweise	Please note "Instructions for Pharmacy (Tissue)".
Rechtsbehelf	Contradiction
Kurztext	• Permission to import tissue • Tissues and tissue preparations may only be imported by an importing tissue establishment which carries out this activity on a commercial and professional basis. • Tissue establishment requires a contract with a third country supplier for import. • A written, informal application must be submitted.
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority

Modul	Sachverhalt
Formulare	
Ursprungsportal	Hamburg Service, Hamburg Service (Currently this link is only available in german)