Freie Hansestadt Bremen

Apply for over-the-counter certificates for active in vitro diagnostics

Are you responsible for placing an in-vitro diagnostic device on the market and would like to export it outside the European Union? Then the respective competent authority will issue a certificate according to §10 MPDG upon your request.

Competent Department

- Die Senatorin für Gesundheit, Frauen und Verbraucherschutz | Referat 23 Pharmazie, Medizinprodukte und Umwelthygiene

Contact Person

- **E-Mail für Medizinprodukte**

  E-Mail für Medizinprodukte

  E-mail

Basic information

As a manufacturer of in vitro diagnostics or its authorized representative, you can apply for the issuance of a certificate of free sale for export purposes. The certificate of free sale confirms that the manufacturer or authorized representative has its registered office in Germany and that the product in question can be traded within the Union.

Requirements

- Product must be placed on the market according to Article 5 Article 10 of Regulation (EU) 2017/746 of an in vitro diagnostic medical device.
- Only manufacturers and authorized representatives based in Germany can apply here for a certificate of free sale for in vitro diagnostic medical devices

Procedure

1. You submit the required documents to the competent authority by post or electronically.
2. The competent authority checks the documents.

3. The competent authority requests additional documents if necessary.
4. The competent authority issues the certificate.

Legal bases

- §10 Medizinprodukterecht-Durchführungsgesetz (MPDG)
- Artikel 55 Verordnung über In-Vitro-Diagnostika (Verordnung (EU) 2017/746)

What deadlines must be paid attention to?

The certificate of marketability according to § 10 MPDG does not contain any time limits. It confirms the status as of the date of issue.
Each recipient country decides for itself on the duration of the certificate's validity.