Freie Hansestadt Bremen

Apply for over-the-counter certificates for active medical devices

Are you responsible for placing a medical device on the market and would like to export it outside the 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 medical devices 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 and Article 10 of Regulation (EU) 2017/745 of a medical device.
- Only manufacturers and authorized representatives based in Germany can apply here for a certificate of free sale for medical devices.

What documents do I need?

- Declaration of Conformity
- Product list
- Certificate(s) from the Notified Body(ies)

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)

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.