

Apply for over-the-counter certificates for non-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 upon your request.

Competent Department

- [Die Senatorin für Gesundheit, Frauen und Verbraucherschutz | Referat 23 Pharmazie, Umwelthygiene und Toxikologie](#)

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 in accordance with 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

Procedure

1. You submit your application.
2. The competent authority checks the documents.
3. The competent authority requests documents if necessary.

4. The competent authority issues the certificate.

Legal bases

- [§10 Medizinprodukte-Durchführungsgesetz \(MPDG\)](#)
- [Verordnung \(EU\) 2017/745 des Europäischen Parlaments und des Rates über Medizinprodukte](#)

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.