



Law Firm Jakob

Legal Guide

for Import, Export and Trade with MedTech Products

Are you a manufacturer, EU authorized representative, or distributor of medical technology products planning to export, import, or market medical devices?



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<https://www.anwaltskanzlei-jakob.com/en/product-compliance/medical-devices>

We explain why this legal guide is important for your company:

Entering the European Union (EU) market with medical technology products is subject to complex regulatory frameworks. If these requirements are not met, your product will not be approved for the European market. In addition, there may be serious consequences and liability issues for companies.

With proper contract drafting, you can secure civil law advantages and mitigate risks. This includes international supply contracts, distribution agreements, and transport contracts that best protect your interests.

Knowledge of customs law—such as special customs procedures or rules of origin—can lead to customs reliefs. Through careful preparation of export procedures and internal export controls, you can avoid costly and serious errors.

With this Legal guide, you receive a sound overview for your entire supply chain.

Contents of this Guide:

I. Market Access

II. Import

III. Export

IV. Contracts

Please note: The requirements vary considerably depending on the product and destination country. For an individual assessment, we will gladly advise you personally. This guide serves as an overview and has been prepared to the best of our knowledge and professional care. However, no guarantee or liability is assumed for its accuracy or completeness.



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I. Requirements for Market Access of MedTech in the EU

1. What are the regulatory specifics?

- *EU Regulation 2017/745 on Medical Devices (MDR)*
- *EU Regulation 2017/746 on In Vitro Diagnostic Medical Devices (IVDR)*
- *In Germany: Medical Devices Implementation Act (MPDG)*

2. Is it a medical device or a product similar to a medical device?

The manufacturer must demonstrate that the intended principal effect is not achieved by pharmacological, immunological, or metabolic means. Otherwise, the product may be classified as a medicinal product, which does not fall under the scope of the MDR/IVDR.

3. Does my product meet the basic safety and performance requirements of the MDR / IVDR according to Annex I?

For example: substances, radiation, labelling, instructions for use, etc.

The basic safety and performance requirements must be fully complied with without exception. If personal injury occurs, the manufacturer is automatically liable under product liability law if the conditions set out in Annex I have not been met.

4. Is my technical documentation according to Annex II and the technical documentation on a post-market surveillance system (PMS) according to Annex III complete?

A verifiable quality management system and risk management system are mandatory requirements under the MDR and IVDR. In addition, manufacturers and EU authorized representatives must designate a Qualified Person / Person Responsible for Regulatory Compliance (PRRC).

5. Do I comply with the key European standards?

Applicable standards must be researched individually for each product. These include, for example:

- *EN ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes*
- *EN ISO 14971 – Medical devices – Application of risk management to medical devices*
- *EN IEC 62366 – Medical devices – Application of usability engineering to medical devices*
- *EN IEC 62304 – Medical device software – Software life cycle processes*
- *EN ISO 14155 – Clinical investigation of medical devices on human subjects – Good clinical practice*
- *In addition, there are other safety-related standards and guidelines concerning cybersecurity*

Note: Harmonized standards create a presumption of conformity and must not be undercut. They represent the minimum standard. Compliance with these standards gives rise to the presumption that the product conforms to EU requirements. The current state of the art must always be taken into account

6. Has the risk-based classification been carried out?

The manufacturer must perform a risk-based classification of its products (Classes I, IIa, IIb, and III under the MDR and Classes A–D under the IVDR). This classification is carried out in accordance with Annex VIII and also determines whether a Notified Body must be involved.

7. Have the following registrations been made?

- *Application for a unique UDI code (Unique Device Identification) by the manufacturer or EU authorized representative through an issuing entity recognized by the European Commission, e.g., GS1, HIBCC, etc.*
- *One-time registration in the Actor Registration Module of EUDAMED by manufacturers, EU authorized representatives, and importers, and obtaining the Single Registration Number (SRN) before carrying out the conformity assessment procedure.*

8. Has a conformity assessment procedure been successfully carried out?

Based on the technical documentation and clinical evaluation, the manufacturer conducts the conformity assessment procedure—either independently or, in most cases, in cooperation with the Notified Body.

In addition to the MDR and IVDR, other EU legal acts may also need to be complied with and indicated, such as the Low Voltage Directive, the Machinery Directive, the REACH Regulation, the WEEE Directive, or the Battery Act (BattG).

9. Have the following measures been carried out?

- *Preparation of a declaration of conformity after successful completion of the conformity assessment procedure*
- *Affixing of the CE marking on the product*
- *Product labelling and instructions for use*

10. Has product registration in the EUDAMED database been completed?

Manufacturers, authorized representatives, and importers must register in EUDAMED using the European Medical Device Nomenclature (EMDN) and UDI. This is a mandatory step before placing the product on the EU market.

11. Market Surveillance (PMS)

Among the general obligations of manufacturers is the establishment of a risk management system as well as a quality management system that includes a post-market surveillance process (PMS) following the product's placement on the EU market. This process is intended to ensure the implementation of corrective and preventive measures. Distributors and importers must also cooperate with manufacturers or their authorized representatives to achieve an appropriate level of product traceability. This includes comprehensive documentation of products placed on the market and the prompt forwarding of complaints, reports, or incidents.

II. Imports of MedTech and Raw Materials

1. What requirements apply for imports?

- *For import into the EU, the customs declarant must apply for an EORI number (Economic Operators Registration and Identification) and indicate it in the customs declaration.*
- *The importer or customs declarant must determine the correct customs tariff number for the medical device in accordance with the nomenclature of the EU Common Customs Tariff.*
- *The importer or customs declarant must keep all documents required for import available.*

2. Who files the customs declaration?

The importer can:

- *file directly,*
- *appoint a direct representative (if established in the EU), or*
- *appoint an indirect representative (if outside the EU, e.g., freight forwarder).*

3. What duties must be paid when importing medical devices into the EU?

For finished MedTech products classified under tariff headings 9018 and 9022 of the European Customs Tariff, the customs duty rate for import into the EU is 0%, and the import VAT for imports via Germany is 19%.

Note: Pre-products, materials, and components used in the manufacture of medical technology that fall outside tariff headings 9018 and 9022 of the European Customs Tariff are often subject to customs duties.

Example: TARIC code 7606 12 92 25 0 – alloyed aluminium sheet less than 3 mm thick – is subject to an EU third-country customs duty of 7.5%, and for goods from non-preferential manufacturers in China, an additional 24.6% anti-dumping duty applies.

4. Can anti-dumping or countervailing duties apply?

For certain pre-products and materials, there are varying levels of anti-dumping duties upon import into the EU, depending on the material composition, country of origin, and specific manufacturer.

Examples: Stainless steel, aluminium in specific forms, plastics, composite materials such as fiberglass and carbon fibre, as well as pipe fittings and seamless tubes, etc.

Note: It is advisable to review the relevant EU anti-dumping regulations before importing.

5. Are import duties generally payable when importing goods and raw materials?

In principle, yes. However, there are special customs procedures that can result in import duties either not being charged or being deferred until a later date. These may include the customs warehousing procedure, the transit procedure, or inward and outward processing. These special procedures are subject to specific strict requirements and must be applied no later than at the time of import.

6. Which documents must be available for the customs declaration of MedTech products?

- *Commercial invoice*
- *Packing list*
- *Transport documents (CMR consignment note, Air Waybill, Sea Waybill)*
- *Declaration of conformity*
- *Technical documentation*
- *If applicable, certificate of conformity*

7. What errors can lead to the seizure of medical devices?

Incorrect or missing declarations of conformity, technical documentation, certificates of conformity, product labelling, or instructions for use result in the medical device being non-compliant with EU regulations and therefore not permitted to be imported into the EU single market.

8. What are the consequences of incorrect or missing documents, product labelling, or an incorrect customs tariff number during import?

The goods will be seized. They must either be re-exported or destroyed. A notification may also be sent to the EUDAMED system. Regulatory investigations may follow. For example, if an incorrect customs tariff number was declared for raw materials, this can lead to subsequent collection of import duties and even criminal proceedings.

9. When does my medical device have EU origin?

The so-called non-preferential origin of goods for export can be proven with a certificate of origin issued by the Chambers of Industry and Commerce (IHK). This certifies that the processing or manufacturing operations carried out on a product within the EU are considered sufficient to confer origin status, meaning the product qualifies as one of EU origin.

In contrast, the label “Made in the EU” on a product does not provide any legal statement regarding its origin status.

This must be distinguished from preferential proofs of origin, such as the formal EUR.1 movement certificate or the informal statement on origin under EU free trade agreements with Japan, Canada, the UK, and other countries. These confirm that the relevant processing list rules have been met, allowing the product to be imported into the destination country with preferential tariff treatment.

III. The Export of MedTech Products and its Pitfalls

1. Do I always have to check for sanctions when exporting?

Yes, this is absolutely necessary, regardless of the country to which the medical device is being delivered. Sanctions apply to individuals, companies, and public institutions, even if those persons or shareholders are located in another state or territory. In addition, existing embargoes must be checked. These include prohibitions and restrictions on business relations and certain actions, as well as restrictive exceptions. To prevent the unintentional circumvention of sanctions, the implementation of an Internal Compliance Program (ICP) is strongly recommended.

2. Is U.S. export control law relevant for me?

U.S. export control law is relevant in the export of medical devices whenever there is a connection to U.S. jurisdiction, known as a U.S. nexus. Such a connection may exist, for example, if the medical device contains controlled U.S. components or if U.S. persons are involved. In such cases, U.S. export control regulations should be reviewed due to their extraterritorial effect, especially if business relationships with the U.S. exist or if entry into the United States is not to be jeopardized. Violations of U.S. export control law can lead to severe penalties and adverse consequences.

3. Does the export of medical devices require authorization?

Most medical devices are not classified as dual-use goods - items with both civilian and military applications - so they can generally be exported without a license. However, there are certain medical devices for which an individual export license or at least a general license may be required. For exports to sanctioned countries, specific exemptions may apply.

Whether the export is license-free or subject to authorization requirements - or whether exemptions can be used - must be carefully assessed on a case-by-case basis. Violations of EU foreign trade law can lead to severe penalties and adverse consequences. To prevent this, it is advisable to implement an Internal Compliance Program (ICP).

4. How does the export process generally work?

The export procedure is basically structured in two stages. First, the medical device must be declared for export at the export customs office responsible for the exporter and presented there. After submitting the customs declaration, the medical device may be transported to the exit customs office at the EU's external border, where it must again be presented. Only then can it officially leave the EU. There are exceptions to the obligation to present the medical device - known as presentation "Gestellung" - but these must be approved in advance.

5. What must I consider for market access outside the EU?

Successful market entry in the destination country requires compliance with the local legal requirements. In most countries, registration with the competent regulatory authority and the appointment of a local contact person or authorized representative are also mandatory. Approval procedures and requirements can vary significantly. In addition to the market regulatory requirements in the destination country, the local customs regulations governing the import of the specific shipments are also relevant.

IV. Contracts for MedTech and Raw Materials That Lead You to Success

1. Are the choice of law and jurisdiction important in purchase and supply contracts?

Yes, the choice of law determines which legal system governs the business relationship. Legal systems differ greatly from one another. When drafting a contract, the advantages and disadvantages, as well as possible adjustments - where permissible under the applicable legal system - should be carefully considered. The choice of jurisdiction determines which court will have international authority to decide disputes, which can be decisive for the outcome of the case. Not every judgment is enforceable in every country worldwide. Furthermore, there is also the option to agree on an arbitration clause.

2. Which provisions should a purchase and supply contract for MedTech products ideally include?

- *Clear identification of the contracting parties*
- *Precise specifications of the goods*
- *Provisions regarding documentation*
- *Fixed or determinable price*
- *Payment terms*
- *Delivery conditions, e.g., Incoterms®*
- *Warranty / liability*
- *Non-disclosure agreement (NDA)*
- *Choice of law / jurisdiction*

3. Why is it advisable to include Incoterms® in the purchase and supply contract?

Incoterms® are internationally recognized delivery terms used in global trade, such as EXW, FOB, CIF, etc. Their use provides significantly greater clarity and transparency for both contracting parties. They regulate the following key aspects related to delivery:

- ***Rights and obligations***
- ***Transfer of risk***
- ***Transfer of costs***

Example: Who bears the risk of defective packaging? Who bears the risk if the MedTech product is damaged during transport? How must the delivery be carried out? Who is responsible for taking out transport insurance? Who must handle export clearance? Who pays the import duties? Who organizes the transport and up to what point? etc.

4. When are distribution agreements useful?

Distribution agreements are useful for organizing the long-term and targeted sale of MedTech products, for example, within specific sales territories—when the seller does not have its own branch or subsidiary in the target market. A distinction is generally made between distributors and commercial agents.

Note: Both models involve different obligations and risks for the contracting parties, particularly with regard to termination protection, non-compete clauses, and compensation claims.

5. Are there any special considerations for the transport of MedTech products?

- *Depending on the mode of transport, there are maximum liability limits for loss, damage, and delay of goods. For road transport, the maximum liability is 8.33 Special Drawing Rights (SDR; 1 SDR ≈ €1.16) per kg, for air transport 26 SDR, and for sea transport 2 SDR.*

Note: In certain cases, it is advisable to take out cargo insurance.

- *Companies should document the outgoing goods inspection as precisely as possible, since they must be able to prove in the event of damage that the MedTech goods were undamaged at the time they were handed over to the carrier.*
- *If batteries are packed in or together with a MedTech product, the entire package must be classified as hazardous goods. In this case, hazardous goods regulations such as ADR, IATA-DGR, or the IMDG Code must be checked for correct labelling, issuance of a transport document, and any applicable exemptions.*
- *Load securing must always be carried out by the sender and never by the carrier, unless it has been expressly agreed in the transport contract that the carrier assumes this responsibility.*

Note: An above-average number of transport damages result from deficiencies in load securing.