

# 16 tips for doing business on the European market for Medical Devices and Laboratory Equipment

The medical and laboratory equipment market is one of the most complicated European markets due to specific requirements set by the European Commission's (EC) committee for medical devices. If an exporter does not meet those requirements it is almost impossible to do business in Europe.

Continue reading below if you want to become a successful exporter to the European Union (EU).

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## 1. Develop a sound business plan

For every business, it is important to write a sound business plan and a financial plan. A business plan helps you to steer your business in the right direction, and it is often necessary in order to attract external funding. Pay special attention to a marketing plan for each of your products. What are your objectives? What is the market segment and who is your target group? What type of certification and documentation is needed? What is your price strategy? How will you promote and distribute your product? What is your budget and how will you evaluate your performance?

## 2. Develop a Market Entry Strategy

Successful access to the European (or any other) market is easier when you have developed an Export Marketing Plan (EMP) in advance. Your EMP should be based on profound market research and start with an internal analysis of your own business followed by an external analysis of your target market(s). Based on those analyses, you can define your core competencies, action points, market attractiveness and competitive power. This leads to a Market Entry Strategy (MES), which includes sales objectives/export targets, marketing mix, budget, forecast and a clear action plan.

## 3. Obtain ISO Certifications

European buyers of medical devices and laboratory equipment only buy from manufacturers that have the obligatory certifications such as [ISO 13485](#) (quality management systems for medical devices, requirements for regulatory purposes), [ISO 14971](#) (application of risk management to medical devices), [ISO 17664](#) (providing information for the processing of resterilisable medical devices) and others like [ISO 60601](#) for medical electronic

equipment.

To obtain these certifications, auditors of registered companies (such as [TÜV SÜD](#), [SGS](#), [DNV](#) and [Dekra](#)) will help you set up a Quality Management System (QMS). Every change in production or product should be registered and the auditor should be informed. He or she can then decide to carry out a new audit or allow you to carry on based on written consensus.

## 4. Get all the necessary CE certifications

European buyers of medical devices and laboratory equipment require that all the products they buy are [CE Certified](#). As a manufacturer, you have to undergo an extensive audit carried out by an independent expert before your product is allowed to enter the European market. When your products are classified in a specific class (higher than class 1A), you need to be audited by an official acknowledged [Notified Body \(NB\)](#). Every registered NB has a Code number (CE 0123 etc.). Only in case of a simple class 1 non-sterile product, a self-declaration of conformity is enough.

Read more about CE Marking in '[CE – Marking: Passport to Europe for Medical Devices](#)'.

## 5. Be aware of the Harmonized Standards

The European Union (EU) has harmonised its standards for most medical devices. Standards are technical specifications which define requirements for products, production processes, services and test methods. You can use the harmonised standards to demonstrate that your product and processes comply with the relevant EU legislation. See the [list of titles and references of harmonised standards under the Medical Device Directive](#) for a complete overview of all standards.

## 6. Appoint an Authorized Representative (obligatory)

Every manufacturer of medical devices and laboratory equipment is required to have an Authorized Representative (AR) based in an EU member state. The AR should be experienced and aware of your Quality Management System (QMS), and have an official copy (verified and certified by the Notified Body) of the complete technical file of each product they buy from the manufacturer. In case of a severe complaint from the end-user, the European distributor has to contact the AR, who should then start the recall procedure and undertake the necessary steps by informing the manufacturer in order to find out who is responsible.

## 7. Implement Corporate Social Responsibility (CSR) guidelines

It is a big advantage if you can show potential EU buyers that you as manufacturer have implemented CSR guidelines. Compliance with these guidelines means that your production facility is friendly for people (no child or forced labour, safe work place, etcetera) and for the environment (green manufacturing).

## 8. Communicate properly

You can distinguish yourself by excellent communication, as this is often a weak point for manufacturers from developing countries. It is very important that you respond quickly (within 1 day) to emails and always inform your buyer about delivery dates and time. You should use all available media (phone, email, Skype) to convey your message and be sure that everything works 100% from a technical standpoint. In case of a language barrier, it is recommended that you make use of the services of a translator who can assist you in writing clear and understandable texts.

## 9. Know the market structures

To do business with European buyers it is important to understand how the market is structured and what type of buyers you should focus on. Even though it is complicated, you need to find out what the most important

trade channels are. Does the trade for your product and in your target market run via agents, importers or distributors? Or should you do business directly with end-users such as hospitals and private clinics. Read [CBI's study on the channels for medical and laboratory devices on the European market](#) for more information.

## 10. Be aware of the geographical and political situation

If you want to export goods, it is important to take different aspects of your target market into consideration: distance, public transport, population size and level of healthcare.

Language is important too. There are several regions in Europe in which they speak the same language. It is often easier to do business in the same language-region:

- German: Germany, Austria, eastern part of Switzerland.
- French: France, southern part of Belgium (Wallonia), western part of Switzerland
- Russian: Baltic states, border area Finland-Russia, Belarus, etc.
- English: United Kingdom, Ireland, Scotland.
- Dutch: Netherlands, northern part of Belgium (Flanders).

## 11. Be clear in your Terms and Conditions

Be prepared to negotiate the terms and conditions with the buyer. Don't make the mistake of underestimating the essence of the [Incoterms](#) (short for International Commercial Terms). Make sure that you accurately understand their meaning. When in doubt, contact an expert in this matter.

Potential European buyers want to reduce the risks by using the most favourable Incoterms. Most of the buyers prefer to use FOB (Free on Board) or CIF (Costs, Insurance and Freight). Freight costs are an important aspect of the total logistical costs and vary between 3-10% of the value of the goods.

## 12. Know your specific (end-user) market

Most of the EU medical markets have their own 'programme of demands'. Your distributor in a particular country can inform you about it. Some buyers have an even more strict policy. This can, for example, apply to products for sterilisation, or for bigger electronic equipment.

## 13. Know your potential customer

When you meet a potential European importer at a trade fair or conference, you have the opportunity to get a good understanding of their company. A questionnaire is a good means to gather the information. Topics should include contact details, corporate data, product portfolio, sales and marketing data, territorial coverage and customers. If the interviewee is willing to share this information with you, you know you are on the right track with this contact. At the same time, you should be prepared to share such information about your own company, as a good prospect will also be interested in a better insight into your company.

## 14. Provide clinical studies and publications

Manufacturers of highly sophisticated medical devices (class IIb and III) should be able to provide European buyers with clinical studies, accompanied by publications in internationally acknowledged medical magazines. Through these studies and publications, the buyer can convince the end-user that these products are safe for the patient, safe in use, and of a high quality.

Highly sophisticated medical devices are found in all market segments, and include implantable devices like stents, heart valves, vessel grafts, artificial joints and catheters for parenteral nutrition, as well as products used in open-heart surgeries, and extra corporeal circuits in combination with the heart-lung machine pump.

## 15. Pay attention to packaging and labelling

As stated in the [CE Medical Device Directive 93/42/EEC](#), special attention should be paid to packaging material. Packaging must have profound bacterial barriers and should be strong, protect against damage that may occur during transport and water-resistant.


All sterile devices should have a multi-language label mentioning the product code, batch number manufacturing date, expiration date and the sterilisation media (all according the ISO symbols).

## 16. Consider acting as a Contract Manufacturer or Private Labeller


In some cases, there are possibilities to not just offer a particular product, but to manufacture products especially for your buyer according to his or her specifications. In many cases, manufacturers from developing countries also work as subcontractors, supplying semi-finished products.

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