GUIDELINES OF IMPORTING MEDICAL DEVICES INTO THE EUROPEAN UNION

STEP 1. The manufacturer should first decide if the product concerned is a medical device as defined in Directive 93/42/EEC or an accessory to such a medical device, if it is not excluded from the scope of this Directive and if it therefore comes within the scope of this Directive (MEDEV 2.4/1 Rev. 9 June 2010)


On the 26 September 2012, the EC proposed new rules for Medical Devices and In Vitro Diagnostic Medical Devices. The Medical Device Directive is to become a Regulation. From October 2012, the European Parliament will examine the proposed regulations and negotiate and agree on how they would like the final regulations. The Council, which brings together the governments of the 27 Member States of the European Union, will do the same. The process is undergoing a 10 week public consultation starting from 12 November 2012

The revised regulatory framework for medical devices is comprised of the following:

i. A proposal for a Regulation on medical devices (to replace: Directive 90/385/EEC regarding active implantable medical devices and Directive 93/42/EEC regarding medical devices);


The new regulation:

- Requires manufacturers to have a 'qualified person' with expert knowledge with regulatory responsibility within their organisation;
- Introduces a risk-based system of Unique Device Identification - the details have not yet been agreed but this is highly likely to first apply to high-risk devices and only later apply to class I and II(a) devices;
- Requires registration of the Devices and Manufacturers will need to register on a central European database;
- Requires stricter audit of notified bodies, which may mean tighter scrutiny of the conformity assessment of class II(a) devices;
- Stricter requirements on Manufacturers to perform a thorough clinical evaluation; and
- Requires Manufacturers to report incidents to a central European database.

When agreement is reached between the European Parliament and the Council, the two regulations will be adopted in 2014 (estimate) and the regulations will be enforced in 2017 – 2019 (estimate) in various European Countries
All medical devices sold within the European Union (EU) have to comply with the requirements of the Medical Devices Directive 93/42/EEC and bear the CE mark.

**MEDICAL DEVICE**

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

**The Medical Devices Directive 93/42/EEC**

- Specifies “essential requirements” which must be met before any device can be placed on the market;
- Introduces controls covering the safety, performance, specification, design, manufacture and packaging of devices;
- Specifies requirements for assessment of clinical investigation protocols, and the evaluation of any adverse incidents that occur;
- Introduces a system of assessment of clinical investigation protocols, which is matched to the degree of risk inherent in the device;
- Empowers a Competent Authority to identify and designate “notified bodies” who check and verify that devices meet the relevant essential requirements.

The Medical Devices Directive 93/42/EEC places obligation to Manufacturers to ensure that their devices are safe and fit for their intended purpose before they are CE marked and placed on the market in any European Commission member state.

The CE mark that appears on a medical device or on its packaging means that the device satisfies the relevant essential requirements and is fit for its intended purpose as specified by the manufacturer. All devices, (except custom-made devices, those intended for clinical investigations and devices for performance evaluation) whether used in private or public hospitals and nursing homes or sold in retail outlets, must carry the CE marking.

This regulatory framework is for market access, international trade relations and regulatory convergence in the European Countries, all aiming to ensure the highest level of patient safety while promoting the innovation and the competitiveness of this sector.

There are 31 European countries regulated by the Medical Devices Directive 93/42/EEC and the CE Marking, out of which 27 are in the EU. Liechtenstein, Norway and Iceland are not members of the
EU; they are signatories of the European Economic Area (EEA). Switzerland is also not a member of the European Union or a signatory to the EEA but it has adopted the Medical Devices Directive 93/42/EEC and the CE Marking in its National Law. Three more EU candidate countries Croatia, Macedonia and Turkey fully recognise the Medical Devices Directive 93/42/EEC and the CE marking.

CE MARKING

What is CE Marking (CE Mark)?

CE Marking is the symbol as shown above. The letters "CE" are the abbreviation of French phrase "ConformitéEuropéene" which literally means "European Conformity". The term initially used was "EC Mark" and it was officially replaced by "CE Marking" in the Directive 93/68/EEC in 1993. "CE Marking" is now used in all EU official documents.

CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislations, in practice by many of the so-called Product Directives.*

*Product Directives contain the "essential requirements" and/or "performance levels" and "Harmonized Standards" to which the products must conform. Harmonized Standards are the technical specifications (European Standards or Harmonization Documents) which are established by several European standards agencies (CEN, CENELEC, etc).

CEN stands for European Committee for Standardization.

CENELEC stands for European Committee for Electrotechnical Standardization.

CE Marking on a product indicates to governmental officials that the product may be legally placed on the market in their country.

CE Marking on a product ensures the free movement of the product within the EFTA & European Union (EU) single market (total 30 countries), and

CE Marking on a product permits the withdrawal of the non-conforming products by customs and enforcement/vigilance authorities.

General principles of the CE marking
The CE marking shall be affixed only by the manufacturer or his authorised representative.

The CE marking shall be affixed only to products to which its affixing is provided for by specific Community harmonisation legislation, and shall not be affixed to any other product.

By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set out in the relevant Community harmonisation legislation providing for its affixing.

The CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant Community harmonisation legislation providing for its affixing.

The affixing to a product of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

Member States shall ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

Along with more directives' becoming effective, more and more products are required to bear the CE Marking for gaining access to the EFTA & European Union market. However, many non-EU exporters are still unaware of or unsure about this fact and its impact on their business.

CE marking is an important requirement for anyone exporting to the European Economic Area (EEA), that is, all the EU member states and the associated countries Iceland, Liechtenstein and Norway. Many products are only granted formal access to EU markets with CE marking and it is illegal to trade those products in the EU without the mark. It must also be noted that it is absolutely forbidden to affix the CE mark to products not covered by any European Directive requiring CE marking.

Process for CE Marking Certification for Medical Devices in Europe
STEP 2 \textbf{CLASSIFICATION}

Once the product has been determined as a Medical Device, the next step is to determine its classification.

A medical device (MD) may be classified as

- Class I Non-Sterile, Non-Measuring
- Class 1 Sterile, Measuring (Requires intervention of Notified Bodies)

http://www2.emergogroup.com/download-literature
• Class IIa, IIb and III (Require intervention of Notified Bodies)

Class III medical devices cover the highest risk products. The higher the classification the greater the level of assessment required.

The classification rules are found in Annex IX of the MDD 93/42/EEC Directive. This annex includes definitions of the terminology used in the classification rules. Classification of a medical device will depend on a series of factors, including:

• How long the device is intended to be in continuous use,
• Whether or not the device is invasive or surgically invasive,
• Whether the device is implantable or active,
• Whether or not the device contains a substance, which in its own right is considered to be a medicinal substance and has action ancillary to that of the device.

It is usually the Intended Purpose for Use that determines the class of the medical device and not the particular technical characteristics of the device.

It is the Intended Purpose for Use, assigned by the manufacturer to the device that determines the class of the medical device and not the class assigned to other similar products manufactured by the same manufacturer or different manufacturers. For instance, two sutures that have the same composition may well have different Intended Purpose.

A manufacturer may successfully avoid the particular higher classification by clearly define on the labelling the Intended Purpose in such a way that the device falls into the lower class!

STEP 3 QUALITY MANAGEMENT SYSTEM (QMS)

The next step for the Manufacturer is to implement the Quality Management System (QMS) in accordance with Annex II or Annex V. Most companies apply the ISO 13485:2005 standard to achieve the QMS compliance, i.e., the ISO 13485:2005 is not mandatory but its certification presumes compliance to Annex II and V.

• For Class 1 Non Sterile, Non-Measuring Devices such as Examination Gloves, do not need to comply fully to a QMS, i.e. need not be audited to a full QMS. This is a self-declared conformity.
• Manufacturers of Class 1 Sterile, Class IIa, Class IIb and Class III Medical Devices must operate under a QMS.
• The implementation of the QMS may take between 3 – 6 months.
• The Quality Management system must be audited by a Notified Body selected by the Manufacturer

STEP 4 TECHNICAL FILE

While the implementation of the QMS is in progress, the Manufacturer may prepare the Technical File.
• Technical File provides detailed information demonstrating compliance with the Medical Devices Directive 93/42/EEC.
• Technical File is required for all Medical Devices including class 1.
• For Class III Medical Devices, this is called the Design Dossier.
• The Technical Files and the Design Dossiers are audited by independent companies known as Notified Bodies authorised by the EU Member State Ministry of Health. The Manufacturer will select its own Notified Body for the review of its technical files for the audit of the QMS.

STEP 5 APPOINT AUTHORISED REPRESENTATIVE

Manufacturers are required to appoint an Authorised Representative in Europe if the business is not located in Europe. An Authorised Representative is also known as the EC Rep.

• The EC Rep must be qualified to handle regulatory matters. The EC Rep is a regulatory liaison between the Manufacturer and the European Ministry of Health of the respective European country called the Competent Authority.
• Regardless of the Medical Device Classification, Manufacturers are required to appoint the EC Rep located in Europe. The ER Rep may also carry out other responsibilities pertaining to the Medical Device Regulations as delegated by the Manufacturer. Tasks may include, product registration, incident reporting, assistance with recalls, change to Competent Authority etc.
• The EC Rep will have full access to the Technical File (or Design Dossier) if a review is requested by the Competent Authority.
• The EC Rep name and address must appear on the labelling.
• Manufacturers may consider appointing Distributors to undertake the role of EC Reps and must carefully choose the EC Rep base on capability and mandatory responsibilities and be aware that the Technical Files which is a proprietary document must be made available which can present problems with multiple Distributors in many different countries.

STEP 6 AUDIT OF QMS AND Technical FILE/DESIGN DOSSIER

The QMS must be audited and the Technical Files/Design Dossier must be reviewed by the Notified Body selected by the Manufacturer.

• Once the Review of Technical File and audit of the QMS is successful, the Notified Body will issue the CE Marking Certification
• Class 1 Non Sterile, Non-Measuring Medical Devices are not issued with the Notified Body CE marking Certificate as conformity is based on self-certification.
• For all Class 1 Medical Devices, the Device must be registered with the Competent Authority where the EC Rep is located.
• Most European countries do not require Classed IIa, IIb and III Medical Devices to be registered as it is already subjected to annual audit by the Notified Body. However, Italy requires all Classes of Medical Devices be registered.

Step 7 DECLARATION OF CONFORMITY
The Declaration of Conformation is a legally binding document prepared by the Manufacturer stating that the Device is in compliance with the applicable Directive.

- One page document on the company’s letterhead
- States that the Company is in compliance
  - Identification of the Device
  - Name of the EC Rep
  - Classification
  - Process of Compliance
  - List the Notified Body CE Marking Certificate Number
- Sign by the Company; an electronic signature is acceptable

The CE Marking may now be affixed.

**STEP 8 LABELLING AND DOCUMENTATION**

There are 31 European Countries and 23 Official languages. Although it is not explicitly addressed in the Medical Device Directive 93/42/EEC, Manufacturers must ensure that the labelling and documentation must comply with the National Laws of the European country where the Medical Devices will be sold except if an exemption has been obtained from the Competent Authority. Labelling and documentation must be done in the official language.

- Translation into the national language is in compliance with the national regulatory requirements.

**STEP 9 MONITOR SAFETY AND EFFICACY**

After CE marking has been obtained and Devices are now placed on the EU market, Manufacturers must continue to monitor the safety and efficacy of the Device/Devices.

- Appropriately handle incident report according to the EU requirement
- Establish an effective marketing surveillance process in place
- Review experience gained
- Implement corrective actions as needed

**IMPORTING**

**Overview**

To import goods into the European Union (EU) from outside the European Union or move them from another EU country you have to:

i. Find the correct commodity code
ii. Pay VAT in some cases
iii. Fill in a VAT return if you’re VAT registered
iv. Register with the respective European Country Department Databases such as the CHIEF system for UK, for importers if you’re exporting outside the EU
v. Declare the goods
vi. Pay duty in some cases
vii. Get a licence for some goods (eg firearms)
viii. Check if the goods are banned from being imported into the European Union or require an import licence

The exact rules for importing depend on whether you’re moving goods from another country in the EU or importing from overseas.

Some businesses use freight forwarding agents to help them with their import procedures.

Malaysia is currently regarded as the Standard Beneficiary Country (17 August 2010) under the Generalised Preferential Scheme (GSP). The Generalised System of Preferences (known as GSP for short) is a scheme whereby a wide range of industrial and agricultural products originating in certain developing countries are given preferential access to the markets of the European Union. Preferential treatment is given in the form of reduced or zero rates of customs duties. The GSP scheme is specifically designed to benefit certain developing countries and integrate them into the world economy.

The EU adopted a new GSP on 31 October 2012. Regulation (EU) 978/2012 of the European Parliament and of the Council. In order to allow ample time for economic operators to adapt to the new scheme, the new preferences will apply as of 1 January 2014.

Until 31 December 2013, the preferences under the previous scheme will continue to apply. Those preferences were defined by Council Regulation (EC) No. 732/2008 and extended until 31 December 2013 by a GSP "Roll-over" Regulation.

- 31 Oct 2012 – New GSP adopted by European Commission
  

- Countries eligible as per the vulnerability criteria Annex VII of Regulation 978/2012 meeting the criteria as per the Article 9(1) of the Regulation for the new GSP
- Countries may request to be granted the special incentive arrangement for sustainable development and good governance under Regulation (EU) No 978/2012 of 31 October 2012
  
- Malaysia has been classified as one of the 12 upper middle income economies for the last 3 years by the World Bank
- Thailand, Indonesia, India, Sri Lanka and Vietnam are among many countries categorised as low and lower middle income partners and they will still enjoy the GSP.