

Medical Technology Regulatory Profile

Western European

Disclaimer

The information contained in this profile is intended for general information purposes only. While this and other profiles on this site are updated periodically, many regulatory systems are subject to change. The list of directives included in this profile is not exhaustive, and not all medical devices are required to be in compliance with each of these Directives. While the 30 countries that are collectively known as the European Economic Area (EEA) make use of the common tenants of a shared medical technology regulatory system, member nations may impose certain other restrictions or requirements on medical technology firms exporting to the region.



I. MARKET OVERVIEW

The European Economic Area (EEA) consists of 27 member states of the European Union (EU) plus Norway, Liechtenstein and Iceland. Collectively these countries have historically formed the largest *regional* export market for U.S. medical device manufacturers and are expected to continue to present excellent opportunities for high-technology medical products. Future market prospects are promising due to the region's aggregate high per capita income, a favorable regulatory environment and an aging population. Economic growth and political and currency stability also make the region an attractive market, which accounts for more than 27 percent of the global medical device market.

The Market for medical devices in the EEA was estimated by Espicom Business Intelligence at about \$US 67 billion in 2009 and the collective market is projected to exceed \$US 81 billion by 2012. Shipments of U.S. medical technology products (excluding IVDs) to the EEA totaled about \$16.3 billion in 2009. Imports (including intra-regional trade) account for roughly 80% of the market. Trade between EEA members dominates the import market, and companies wanting to take advantage of the full potential of EEA member countries need to ensure an effective marketing and distribution network. While European medical technology markets have been impacted by the global economic recession in the short term, beyond the current recession the countries of the EEA are expected to return to growth with leading markets averaging Compound Annual Growth Rate of 6.5 percent to 2014.

EEA Market at a Glance:

Estimated Medical Device Market for 2009:	\$US 67 Billion
Estimated Projected Market for 2012:	\$US 81 Billion
Estimated CAGR:	6.5 Percent

Source: Espicom Business Intelligence World Medical Market Forecasts to 2012

The largest individual markets for U.S. medical device exporters within the EEA include Germany, France, the UK, Italy and Spain which in aggregate represent more than half of the region's medical technology expenditures. Germany is both the biggest exporter and importer in the region. The majority of U.S. medical device manufacturers active in the region market to at least one of these countries.

II. GOVERNMENT AUTHORITIES/INDUSTRY ASSOCIATIONS

An evolutionary process has been underway in Western Europe to develop and enforce procedures covering compliance with directives designed to allow products legally marketed within one member state to move throughout the rest of the EEA. The EEA is a confederation of independent, sovereign nations, each with their own governing bodies and health ministries. However, the EU provides common institutions to which members can delegate some of their sovereignty, allowing decisions on specific matters of joint interest to be made at the pan-European level. There are a number of regional authorities and entities of interest to medical device manufacturers, including competent authorities and notified bodies (see "Current Regulatory Requirements):

European Commission's Directorate General (DG) Health and Consumer Affairs (Sanco):

DG Sanco assumed principle regulatory policy authority from the Enterprise and Industry Directorate Medical Devices Unit within the EU's DG Enterprise in 2010. European Commission, Office BREY 10/173, 1049 Brussels, Belgium. Additional information can be found at:

http://ec.europa.eu/consumers/sectors/medical-devices/documents/index_en.htm

Competent Authorities: By definition, an organization that has the legally delegated or invested authority to perform a designated function. A competent authority is nominated by the government of a member state to monitor and ensure compliance with its provisions. The competent authority is responsible for ensuring only approved medical devices are allowed onto the market. *A list of competent authorities can be found at:*

http://ec.europa.eu/consumers/sectors/medical-devices/links/contact_points_en.htm

Notified Bodies: Notified bodies are independent testing facilities or laboratories authorized by Competent Authorities in the member states to perform conformity assessment tasks specified in directives. See Section III for additional information. *A list of notified bodies can be found through:*

<http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.main>

European Medicines Agency (EMA): The European Medicines Agency (EMA) is a centralized body of the European Union with headquarters in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. EMA is responsible for the scientific evaluation of applications for European marketing authorization for medicinal products. Today it has no

formal responsibilities for medical devices but it may touch upon the sector when looking at Advanced Therapy Medicinal Products (ATMP) combined with medical devices.

<http://www.emea.europa.eu/>

Notable Regional Trade Associations

- *Eucomed* is an “association of associations” and acts as the voice of the medical technology industry and its collection of national trade associations in Europe. Eucomed members include national trade and pan-European product associations and internationally active manufacturers of all types of medical technology. The stated mission of Eucomed is to improve patient and clinician access to modern, innovative and reliable medical technology. *Place des Maïeurs, 2-B-1150, Brussels, Belgium*
<http://www.eucomed.be/>
- *European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)* represents the European radiological, electro-medical and healthcare IT industry in Europe. COCIR is a non-profit trade association founded in 1959. COCIR works with various organizations promoting harmonized standards and fair regulatory control across the world. *Diamant Building, 80 Bd A Reyerslaan, 1030 Brussels, Belgium* <http://www.cocir.org/index.php?mode=0>
- *European Diagnostic Manufacturers Association (EDMA)* is the trade association that represents the In Vitro Diagnostic (IVD) industry active in Europe. *Place des Maïeurs, 2, 1150, Brussels, Belgium* <http://www.edma-ivd.be/>

Other associations can be found at: http://ec.europa.eu/consumers/sectors/medical-devices/links/index_en.htm

Regional Standards Organizations

Standards organizations are entities that develop, coordinate and maintain standards that address the interests of medical device manufacturers and other stakeholders. Numerous product safety standards called “ENs” have been published to support the directives’ requirements. Relevant regional standards organizations in Europe include:

European Committee for Standardization (CEN)

<http://www.cen.eu/cenorm/sectors/sectors/iss/index.asp>

European Committee for Electrotechnical Standardization (Cenelec)

<http://www.cenelec.eu/Cenelec/Homepage.htm>

European Telecommunication Standards Institute (ETSI)

<http://www.etsi.org/WebSite/homepage.aspx>

Additional information on relevant medical device-related organizations, dialogues between interested parties and international cooperation efforts applicable to the EU27 can be found at:

http://ec.europa.eu/consumers/sectors/medical-devices/links/index_en.htm

III. CURRENT REGULATORY REQUIREMENTS

Medical Device Directives (MDD)

The European Union maintains a series of measures known as directives to simplify the movement of goods throughout the European Union (EU) and the European Free Trade Area (EFTA) - the EEA without Switzerland. Directives cover a very wide range of product areas with the primary objective of ensuring that the products are well designed, and safe for the user. The EU developed Medical Device Directives (MDDs) to safeguard public health and ensure conformity to safety and health requirements throughout its member countries and, additionally, to members of the EFTA. The EU's regulatory system for medical devices is generally considered open and transparent, and is largely based on international standards. The central purpose of the MDDs is to harmonize the regulations and administrative provisions among the member states of the EEA governing the safety of medical devices.

To register for the European market, a manufacturer must 1) identify the classification of a product and determine which directive applies to the product; 2) draw up the Technical Documentation File 3) prepare the Declaration of Conformity, and 4) apply CE Marking.

The following are the three primary directives for manufacturers of medical devices:

- *93/42/EEC Concerning Medical Devices:* This directive concerns many medical products defined, in part, as “any instrument... or other article... to be used on human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for any injury or handicap; investigation, replacement, or modification of the anatomy or of a physiological process; 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...”
- *90/385/EEC Active Implantable Medical Devices:* This Directive applies to any active medical device intended to be introduced into the human body and remain after the procedure.
- *98/79/EEC In Vitro Diagnostics Directive:* This directive concerns itself with devices used in vitro for the examination of a specimen derived from the human body, including reagents, instruments and specimen receptacles. IVDs include blood glucose monitoring systems for management of diabetes as well as all other medical diagnostic devices used to test samples derived from the body.
- *For online links to these directives:*

http://ec.europa.eu/consumers/sectors/medical-devices/documents/index_en.htmThe following directives may also apply:

- *2006/95/EC Low Voltage Directive (LVD)*: This Directive concerns products with 50 to 1000 VAC or 75-1500 VDC input.

http://ec.europa.eu/enterprise/sectors/electrical/lvd/index_en.htm

- *2004/108/EC Electro-Magnetic Compatibility (EMC) Directive*: Some medical devices are required to meet this directive that sets the specifications for control of emissions and immunity.
- http://ec.europa.eu/enterprise/sectors/electrical/emc/index_en.htm
- *Machinery Safety Directive: 2006/42*: This directive applies to risks arising from the use of machinery and specific safety components.

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_157/l_15720060609en00240086.pdf
(See also the [Interpretative Document of the Commission's Services on the relation between the revised directives 90/385/EEC and 93/42/EEC and directive 2006/42/EC on machinery](#)).

Directive (2007/47/EC) affecting medical device manufacturers selling in the EU became mandatory in March 2010. This directive amends Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market. It is the first significant modification to the Medical Device Directive since 1993.

In addition, there are others “*Basic Directives*” which apply to all manufacturers. These Basic Directives concern trade, enforcement, liability and other issues. Some of the Basic Directives include:

General Product Safety Directive: Directive 2001/95/EC of 3 December 2001 on General Product

Safety http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm#gpsd Adopted in June 2008, *The New Legislative Package* went into force in 2010. This regulatory “toolbox” affects industrial products, including medical devices. It builds on existing regulatory requirements by simplifying, clarifying and strengthening certain aspects of the single market.

http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index_en.htm **Product Categories**

Medical devices fall into various risk categories in the European system. Class I devices are considered low risk and fall into two groups: those with and without the need for sterilization and/or measuring functions. Class II devices are considered medium-risk, and are divided into two groups: Class IIa, which includes a wide range of devices including diagnostic equipment

and EKGs, and Class IIb which includes somewhat higher risk products that could pose a risk to patient health if they failed to perform properly or adequately. Class III products are considered high-risk (e.g. cardiovascular balloon catheters, heart valves) and require significant clinical trial data before they are approved. Annex IX of MDD 93/42/EEC contains rules designed to help manufacturers classify their products. It is important that products are properly classified before beginning the process of compliance with Directives. Guidelines on product classification can be found at:

http://ec.europa.eu/consumers/sectors/medical-devices/documents/borderline/index_en.htm

CE Marking

Once a product complies with the essential requirements of the MDDs (and other directives, if applicable) and the product has been subject to conformity assessment procedures as provided in these directives, the product may be affixed with a CE Marking. “CE” is an abbreviation of a French phrase “*Conformité Européenne*.” The marking indicates that the manufacturer has complied with all the obligations required by the directive(s). CE Marking provides medical device market access to EEA countries.

Certain products may need to comply with more than one directive before CE Marking can be obtained. If several directives apply, the product must conform to the provisions of all these Directives in order to receive CE Marking. CE Marking does NOT demonstrate *quality* approval but only indicates that the manufacturer has complied with the applicable directive(s).

CE Marking must be affixed to the product, or, when this is not possible to its packaging, and to the accompanying documents by the manufacturer, the authorized representative in the EU27 or, in exceptional cases, by those responsible for placing the product on the market. Where special provisions do not impose specific dimensions, CE Marking must have a height of at least five (5) millimeters. When a Notified Body is used, its identifying number must appear below the CE Marking.

After CE Marking has been obtained, companies must continue to monitor the safety and efficacy of their products and put a post-marketing surveillance program in place. There are often additional requirements in the national laws of the various member states, in particular regarding labeling and translation of instructions for use.

Additional up-to-date details on CE marking legislation are available in the Official Journal of the European Union.

Quality Management System

Annex II (*Declaration of Conformity – Full Quality Assurance System*) or Annex V (*Production Quality Assurance*) of directive 93/42/EEC delineates the Quality Management System (QMS) required for all products (with the exception of Class I non-sterile/non-measuring). Most

companies apply European standard ISO 13485, a quality management system designed specifically for medical devices, to comply with QMS requirements. ISO/EN 13485, published in 2003 and based on the ISO 9001 process model approach, is now fully recognized in many countries and by the Global Harmonization Task Force (GHTF) for compliance with the European Union (EU) CE Marking. ISO/EN 13485 is widely accepted as the international standard to address medical device requirements in many countries around the world, including Canada, Taiwan and Japan.

Certification to ISO/EN 13485 takes place when an accredited third party visits an organization, assesses the quality management system and, if satisfactory, issues a certificate confirming that the organization's quality management system meets the requirements of the standard. Implementation of a QMS on average may take anywhere from 3 or 4 months to a year, depending on the companies size and resources and complexity of the product. (NOTE: while many companies prefer this known approach, ISO/EN 13485 is NOT mandatory and other means can be applied for compliance.)

For QMS compliance for ALL products (including Class I non-sterile non-measuring), a technical file containing information on the safety and efficacy of a device must be created and include, among other information, data on function, means of manufacture, materials used, labeling and risk analysis. Class I non-sterile non-measuring devices may usually 'self-declare' compliance with the MDD instead of being audited. Technical files for Class III devices are referred to as "Design Dossiers", and are more complex and usually require more extensive clinical data.

Notified Bodies

Notified Bodies are independent testing facilities or laboratories authorized by Competent Authorities in the member states to perform the conformity assessment tasks specified in Directives to ISO/EN 13485 and various EU Medical Devices Regulations. Manufacturers and exporters may choose a Notified Body in any EEA member state. Notified Bodies may be authorized for specific industries or specific products.

Options for medical devices with minimal risk include self-certification where the manufacturer prepares a declaration of conformity and affixes the CE Marking to the product. Other products with greater risks call for mandatory involvement of a Notified Body. Devices with even greater risks require tests, audits or additional certificates from a Notified Body before CE Marking can be affixed.

The European Commission's Notified Body Operation Group (NBOG) is an oversight group for Notified Bodies in Europe whose goal is to improve Notified body performance by identifying best practices. It consists of representatives of the European Commission and member state competent authorities. NB-Med is a forum in which notified bodies, the European Commission and industry come together to draft technical recommendations toward this end.

Authorized Representative

Once a manufacturer has an established QMS and a technical dossier, companies that do not maintain a place of business in the EU are required to appoint an authorized representative in Europe (regardless of product classification). The authorized representative (“EC rep) is a regulatory liaison between a company and Competent Authorities (CA), Ministries of Health in European countries. The EC rep can perform a variety of functions including handling product registration, notifications of change, and incident reporting. The EC rep must have access to a manufacturer’s technical files in instances where a review is required by a CA. In some cases a distributor can fulfill the role of EC rep, however *companies are advised to select their EC rep with care* given what is at stake. Distributors may or may not be qualified to function as an EC rep, and it may not be advisable to provide proprietary information to a distributor. Authorized representative’s name and contact information are required on product labels within the EC.

All Class I devices must be registered with the CA in the country where the company’s authorized representative is located. Class IIa, IIb and II devices are usually not required to register as these products are subject to annual inspection by a Notified Body. [Note: There are exceptions – for example, Italy requires registration of ALL products on the Italian market.]

Declaration of Conformity

As a final step, a Declaration of Conformity must be prepared. This document is generally a one-page, legally binding statement on company letterhead stating that a company’s products are in full compliance with the Directives. In addition to a description of the device, the name of the companies’ representative, certification number, name of the Notified Body (where applicable) and route to compliance must be included.

The Declaration of Conformity must contain the following information: product identification; the EU directives with which the product complies; standards used to verify compliance with the directives; name of the Notified Body used (if its use is required by applicable directives – *see Use of a Notified Body* below); signature on behalf of the manufacturer or the authorized representative; and the manufacturer's name and address.

Technical Documentation File

Most Directives require the manufacturer or the authorized representative to provide a Technical Documentation File, demonstrating the technical basis for conformity of the product to the requirements of the directive. The manufacturer must implement internal measures to ensure that the product remains in conformity. This information is intended essentially for the use of competent authorities. The file must be kept at the disposal of national surveillance authorities

(called Designated Authorities for medical devices) for inspection and control purposes, and be available for at least ten years, starting from the production date of the final product.

The main elements comprising a technical documentation file are the following

- A general description of the type and its intended use(s)
- Design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of components, circuits, etc.,
- The explanations necessary to understand the operation of the product
- A list of the standards and solutions adopted to meet the essential requirements,
- The results of the design calculations, risk analysis, investigations, technical tests, etc. carried out,
- A statement indicating whether or not the device incorporates, as an integral part, a substance, or human blood derivative,
- A statement indicating whether or not the device is manufactured utilizing tissues of animal
- The clinical evaluation,
- The draft label and, where appropriate, instructions for use.

Language Requirements

Information provided to a user plays an essential role in avoiding or reducing safety risks. Thus, a user manual is often an essential safety requirement. A user manual must contain all the information required for the correct and safe use of a product. EEA Member States have dictated that their national language(s) must appear on device packaging, labels and user manuals when the product is sold in their country. Advertising slogans, the name of the manufacturer and authorized representative address are exempt from this requirement.ⁱ

Evaluation of Conformity

For most products, depending upon the product and the nature of the risks it presents, there are several routes to evaluation of conformity and the ultimate CE Marking of a product. An assessment must be made and documented in the manufacturer's file before CE marking is affixed and before the product is made available or put into service.

After determining which directive or directives apply to the product and establishment of conformity with the essential requirements for design and manufacturing to the applicable directives, the manufacturer must determine conformity assessment procedures from the options each directive prescribes. The guidelines often use a series of questions about the nature of the product to classify the level of risk. For more information on these guidelines, please visit http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm

European Databank (EUDAMED): Data related to the registration of manufacturers, authorized representatives and devices, certificates issued, modified, supplemented, suspended,

withdrawn or refused, data obtained in accordance with the vigilance procedure and data on clinical investigations will now be collected for the European databank (EUDAMED) and shared among Competent Authorities. EUDAMED will be an information system for exchanging legal information related to the application of European Union Directives on medical devices between the European Commission and the Competent Authorities in the European Union Member States. Its legal basis is laid down in Directives [90/385/EEC](#), [93/42/EEC](#), [98/79/EC](#) and [2000/70/EC](#), but concrete implementation measures were set out much later by [Decision 2010/227/EU](#) of 19 April 2010 on the European Databank on Medical Devices.. The data must be submitted in a standardized format. (This has yet to be determined, although the Eudamed Decision of April 2010 states that the databank must be operational by 1 May 2011). The implementation of Eudamed is particularly important for IVD medical devices manufacturers who will no longer have to give notification to every Member State concerned by the placing on the market of IVDs.

MEDDEV

MEDDEV's are guidance documents issued by the European Commission to provide manufacturers and Notified Bodies assistance in understanding the requirements of the medical devices directive. These guidelines have been elaborated through a process of consultation with Competent Authorities and Commission representatives, Notified Bodies, industry and other interested parties in the medical devices sector. The guidelines are not legally binding. It is recognized that it may be possible or appropriate to comply with the legal requirements. The amendments introduced by Directive 2007/47/EC or previous amending directives are progressively being incorporated in all MEDDEVs. The necessary revision is under way.

Pending Legislation/Regulations/Rules

In 2008 the European Commission announced plans to rework and centralize the European framework of medical device regulation, and in May 2008 the Commission launched a public consultation regarding a possible recast of the Medical Devices Directives. The Commission received hundreds of comments on its questionnaire. A summary report of the responses is published on the Commission's website at http://ec.europa.eu/consumers/sectors/medical-devices/files/recast_docs_2008/responses/responses_public%20consultation_recast_en.pdf

The consensus of the consultation showed that while future action might be needed to simplify and strengthen the regulatory framework for medical devices in Europe, more time is required for the preparation on the various topics which form part of the recast exercise.

A Commission proposal is expected for the first semester 2012, covering all medical devices.

In parallel, the Commission has started the revision process of Directive 98/79/EC. A public consultation on “technical aspects of the revision of the In Vitro Diagnostic medical device Directive” closed in September 2010. About 200 hundreds comments were submitted. The Commission is expected to issue its proposal for the revision of the IVD Directive at the same time as the proposal for the recast of the MDD (early 2012).

A summary report of the responses is published on the Commission's website at

http://ec.europa.eu/consumers/sectors/medical-devices/files/recast_docs_2008/ivd_pc_outcome_en.pdf

Environmental Regulations

In recent years the EU has developed a series of environmental regulations that impact the medical device sector. While the Registration, Evaluation, Authorization and Restriction of Chemicals or *REACH* legislation is not targeted specifically at the medical device industry, many of the substances that will be covered in REACH are used in medical equipment in some form. REACH aims to discourage the use of certain substances that are known carcinogens or mutagens in products, and the regulation requires companies selling products in Europe to disclose if certain substances are contained in the equipment they produce. Currently there are about 45 substances on a so-called candidate list of "substances of very high concern", and six substances of very high concern which will be banned within the next three to five years unless an authorization has been granted to individual companies for their use. REACH is a front burner issue for many medical device manufacturers. Manufacturers must ensure that there is no disruption in supply of their substances.

Medical devices also benefit from a special authorization regime under REACH (article 60 of Regulation 1907/2006).

RoHS is a European Directive regarding 'Restriction of Hazardous Substances' adopted by the European Union back in February 2003. The RoHS Directive and associated regulations came into effect 1 July 2006. RoHS prevents new electrical and electronic equipment containing more than agreed levels of hazardous substance from coming onto the market. Medical devices are not covered today by the RoHS directive but the text is undergoing revision and medical devices will fall under its scope in the future (3 years after entry into force of the text for medical devices, 5 years after entry into force of the text for IVDs). The RoHS Directive will also become a CE-mark Directive requiring the submission of a Declaration of Conformity.

The Commerce Department has followed the adoption and application of the existing RoHS directive and assisted U.S. exporters in understanding the directive. Commerce has also been involved in the revision of the RoHS Directive, calling for a science-based approach to substance restriction and the need for an impact assessment before opening the scope of the Directive.

Others laws such as the Waste Electrical and Electronic Equipment (WEEE) directive require OEMs to dispose of products they manufacture in an environmentally responsible way once the equipment reaches end of life. Medical devices are covered by this directive but with a specific exemption today for “implanted and infected medical devices”.

For complete and up-to-date information on REACH, RoHS and WEEE, please visit the following website: www.buyusa.gov/europeanunion.

Reimbursement

Pricing and reimbursement mechanisms for medical devices (MD) in Western Europe vary by country, and may apply to private and public healthcare, to different product categories and even to different regions within the same country. Efforts to adjust the way MDs are priced in EU countries are underway in an attempt to curb costs, hopefully without the unintended consequence of slowing or preventing access to the latest healthcare technologies.

Generally speaking there are two ways in which medical devices are reimbursed in most European countries, including Germany and France. Either the device is recognized as providing a health benefit in its own right or it is recognized and valued as part of a beneficial procedure. In the first case, reimbursement levels are established for the device itself, however, when a device is recognized as part of a procedure, payment for the device must come from within the budget set for the procedure as a whole.

Reimbursement agencies across Europe have compiled lists of devices and procedures that can be reimbursed, along with an assigned value of reimbursement. Procedures lists in Western Europe are generally based on a version of the Diagnostic-Related Group (DRG) system. DRGs are determined through years of collecting data from hospitals about the treatments they provide from which agencies define an average cost of each procedure. Generally, this is how reimbursement values are derived. If enough healthcare facilities manage to undertake more procedures at a lower cost, then the reimbursement value can be re-examined and possibly reduced.

Many government agencies across Europe have begun assessing medical devices and procedures to determine whether the average costs are justified by the patient outcome. These “health technology assessments (HTAs)” are not standardized across Europe, although they often employ many of the same principles. An HTA considers how well a technology works from the perspective of both the provider and the patient, and compares the device or procedure against alternatives, such as medication. HTAs have a greater scope than the efficacy assessments conducted under the European Medical Devices Directives for CE marking. An HTA might, for example, consider cost and time implications of training and maintenance. HTAs may increase the time and resources needed to bring a product to market in Europe. Supporting data requirements from clinical trials have increased, some of which may not be obtainable until after

CE marking (European medical devices directive place limitations on clinical trials to collecting data to support CE marking).

U.S.-EU Cooperation Impacting Trade

The U.S. Department of Commerce participates in certain forums that work on advancing issues of mutual interests impacting trade in medical devices. The United States and the European Union work towards removing unnecessary differences in regulation by deepening collaboration, sharing best practices and jointly extending expertise to support third-country regulatory efforts through the Transatlantic Economic Council (TEC).

USFDA and DG Sanco have engaged in both bilateral and multilateral discussions to harmonize regulation of medical devices. Officials from the USFDA and the European Commission have discussed a process for recognition of inspection audits. This process will continue through talks with EU member states and the Notified Bodies.

Attachment

Changes Resulting from Directive (2007/47/EC)

The changes noted below mainly impact *Medical Device Directive (MDD): 93/42/EEC*, however Directive 2007/47/EC also impacts the *Active Implantable Medical Device Directive (90/385/EEC)*. Other changes will also apply, and companies are encouraged to consult the Directive.

Clinical data is now required for all devices, including Class I - The new Directive imposes more stringent requirements as to what constitutes "clinical evidence" and mandates stronger enforcement by authorities. The definition of "clinical data" is included and the Essential Requirements includes a requirement for Clinical Evaluation according to Annex X, which has been significantly amended.

Records must be retained for 5+ years - Records must now be maintained for inspection by the Competent Authorities for the useful life of the product or 5 years from date of manufacture, whichever is greater. For implantable devices, records need to be kept for 15 years from the time the last product was manufactured.

Class I (Sterile and Measuring) devices may now choose Annex II - Class I Sterile and Measuring devices will have more flexibility to select a route to compliance as they will be given the option to select a full quality assurance conformity assessment module.

Outsourced design and manufacturing must be more closely monitored - If the design or manufacturing of a device is done by a third party, you must demonstrate that you have adequate controls in place to ensure the continued efficient operation of the supplier's quality system.

Closer inspection of design documentation - Notified Bodies will be required to perform an inspection of design documentation for a representative sample of devices using industry standard statistical techniques and commensurate with the risk of the device.

Appointment of an Authorized Representative (AR) explicitly noted - The AR gets a mandate to act, and be contacted, in lieu of the manufacturer in terms of meeting the obligations by the Directives for all classes of devices.

Software is now clearly defined as an active medical device - It does not matter whether the software is integral with the device or is a standalone product. Software validation will also be an Essential Requirement.

Custom devices now subject to post market surveillance - Custom devices will now require a post-market surveillance system that is reportable to Competent Authorities.

Instructions for Use (IFU) must now be revision controlled - Where appropriate, the new Directive states that the date of issue or latest revision of the IFU must be clearly indicated.

Borderline products - Whether a product is classified as a medicinal product or device will now be determined by the Primary Mode of Action rather than by the Intended Use.