Musculoskeletal Clinical
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European Regulatory Overview

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European Regulatory Overview

I. ESTABLISHMENT OF THE MEDICAL DEVICE DIRECTIVE (MDD)

If you manufacture and export medical devices to the European Union (EU), you need to understand the Medical Device Directive (MDD) and how it affects your organization. Today, compliance to the MDD is mandatory regardless of whether the device is sold, given away, or used in a clinical investigation.

The EU adopted the MDD, Council Directive 93/42/EEC, on June 14, 1993. The establishment of the MDD replaced a patchwork of local laws and regulations with a single unified system. Now manufacturers must demonstrate compliance with the MDD and can thereby have their devices accepted simultaneously across all EU member states.

The purposes of the MDD is to eliminate barriers to trade and to protect public safety with regard to medical devices. The MDD specifies the requirements that medical devices must meet in order to be placed on the market in the EU. The MDD is also accepted by the four member states of the European Free Trade Association (EFTA), which include Iceland, Liechtenstein, Norway and Switzerland. Compliance with the MDD is helpful in obtaining regulatory approval in other countries, such as Australia.

The MDD provides a degree of flexibility by allowing manufacturers the option of choosing from several different conformity assessment routes, but compliance is ultimately indicated in a single manner: the application for a "CE mark" to the device.

II. NEW DIRECTIVES AND CHANGES TO THE MDD

One of the key elements to effective regulation within the health-care industry is incorporating an effective feedback system to allow for a changing environment and to provide a mechanism for improving the system, thus, Article 11 of the MDD requires that "The Commission shall, no later than five years from the date of implementation of this Directive, submit a report to the Council on the operation of the provisions referred to in Article 10 (1), Article 15 (1)…accompanied, if necessary, by appropriate proposals." Subsequently, the member states extended the review to cover not only those aspects referred to in Article 11 but also all elements of the MDD that have given rise to concern and areas in which improvements can be made.

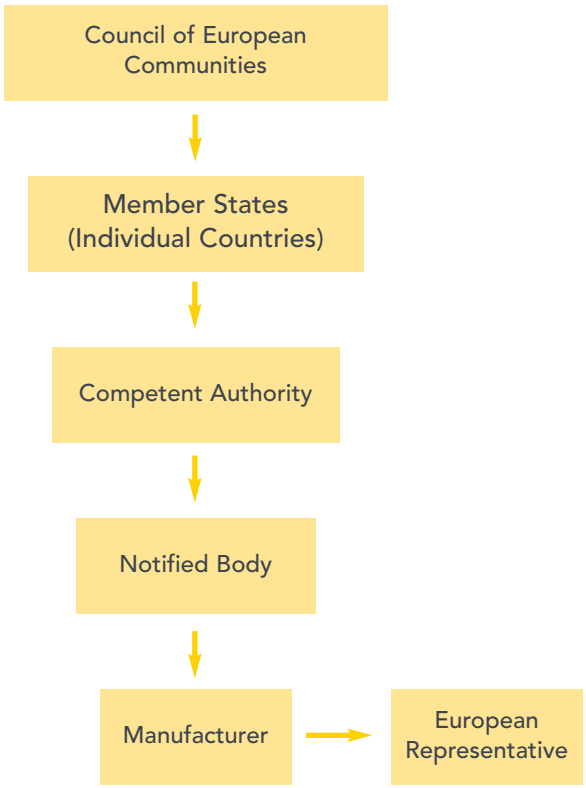
In June 2002, the Commission published a report, which was developed from this review process, on the functioning of the MDD. The report highlighted room for improvement in the MDD. The most important areas addressed were:

- Conformity assessment (if questions arose about the absence of clear rules on design)
- Examination by notified bodies
- The sufficiency and adequacy of clinical data for all classes of devices
- Postmarket surveillance (where better coordination of activities in the area of postmarket surveillance is needed)
- Notified Bodies (in relation to their competence for the tasks for which they are designated and differences in interpretation between Notified Bodies)
- Increased transparency to the general public in relation to the approval of devices

The EU determined that additional regulatory oversight was needed for hip, knee, and shoulder joint replacements because of the numerous adverse events associated with those devices. Council Directive 2005/40/EEC, which was passed on August 11, 2005, specified the additional requirements, which will become effective on September 1, 2007, for all new hip, knee, and shoulder joint replacement devices. For devices that are MDD compliant as of September 1, 2007, the additional requirements are effective either September 1, 2009 or September 1, 2010. In addition, the publication in December 1998 of 98/79/EC, the In Vitro Diagnostic Directive (IVDD), made some changes to the MDD. The amendments are addressed in Article 21 of the IVDD.

III. THE "PLAYERS"

The following diagram shows the organizational hierarchy of the key "players" that regulate and implement the MDD. The responsibilities of those players are described in detail below.



A. Council of European Communities

The Council of European Communities (Council) has primary responsibility for issuing and changing the Directives. This authority is based on Article 95 of the EC Treaty (formerly Article 100a of the Treaty establishing the European Economic Community).

B. Member States (Individual Countries)

The member states have 2 responsibilities:

- Adoption of the MDD into national laws
- Establishing competent authorities

National Laws

To implement the MDD and all subsequent Directives, each member state of the EU adopts national laws. Thus every country in the EU has written and adopted its own law to implement the requirements of the MDD. The MDD also allowed member states to include additional requirements over those specified in the MDD.

For example: 1) almost all member states require that labeling be in their local language, and 2) the German national law (Medizinproduktegesetz [MPG]) requires each company to have a "Safety Officer" and defines numerous requirements related to the position. The MPG also defines specific requirements for the "Medical Device Consultant."

Establishing a Competent Authority

Each member state is responsible for establishing a "Competent Authority." The Competent Authority is equivalent to the United States Food and Drug Administration (FDA).

FROM TIME TO TIME, THERE MAY BE DISAGREEMENTS BETWEEN NOTIFIED BODIES AND/OR MANUFACTURERS REGARDING THE CORRECT CLASSIFICATION OF A DEVICE.

C. Competent Authority

Unlike the FDA, the Competent Authority delegates much of its authority to third parties (each of which is termed a "Notified Body"). The following tasks are the main responsibilities of the Competent Authority:

- ***Providing Notified Body certification:*** The Competent Authority is responsible for certifying and monitoring the Notified Body. Monitoring is performed to ensure that each Notified Body is adequately performing its role as specified in the MDD. If desired, the Competent Authority may certify more than 1 Notified Body.

- ***Performing market surveillance:*** The Competent Authority receives medical device vigilance (MDV) reports on reportable events from manufacturers. These reports are similar to the United States Medical Device Report (MDR). The Competent Authority also forwards information related to MDV reports to other member states.

- ***Deciding the outcome of classification disputes:*** From time to time there may be disagreements between Notified Bodies and/or manufacturers regarding the correct classification of a device. The Competent Authority is the decision maker in resolving such disputes.

- ***Registering certain types of devices:*** The MDD does not require or allow a Notified Body to be involved in the registration of some types of devices, such as class I devices, custom-made devices, procedure packs, or devices used in clinical investigations (see the next section). For these devices, the Competent Authority functions as the registration body.

  In addition, both the Competent Authority and the Notified Body are involved with class III devices that incorporate a medicinal product (drug).

- ***Serving as the notification body for clinical investigations:*** The Competent Authority is responsible for the review and approval of all clinical investigations other than devices that have been CE marked. It is the manufacturers responsibility to submit documentation to the Competent Authority for either approval or denial of these clinical investigations.

D. Notified Body

As previously discussed, each Competent Authority is authorized to establish Notified Bodies. A Notified Body is an independent for-profit organization similar to groups such as the Underwriters Laboratory in the United States. The Notified Body has the following main responsibilities:

- ***Registering manufacturers:*** A Notified Body is responsible for performing certification audits for initial certification and periodic surveillance audits. Surveillance audits are typically performed annually. The audits are intended to verify that the manufacturer has a functioning quality system and complies with the requirements specified in the MDD. Severe lack of compliance during a surveillance audit can lead to the withdrawal of certification, which results in the manufacturer's inability to market devices in the EU.

- ***Registering devices:*** High-risk (class III) devices require special approval from a Notified Body before they can be marketed. For the orthopedic industry, this includes hip, knee, and shoulder joint replacement devices (after the transition period has expired), bioabsorbable devices, and devices that include a drug. For all such class III devices, the approving Notified Body requires that a design dossier including all information necessary to demonstrate that the device is safe and effective be submitted.

  If a design dossier is approved, the Notified Body provides a certificate that allows the device to be CE marked. The certificate is good for a maximum of 5 years and requires renewal before the expiration date to allow the continued marketing of the device.

As noted earlier, the MDD does not require or allow a Notified Body to be involved in the registration of some types of devices, such as class I devices, custom-made devices, procedure packs, or devices used in clinical investigations.

E. Manufacturer

The manufacturer herein is defined as the company named on the product label, even if that manufacturer did not design, produce, or inspect the device. Thus, the manufacturer is responsible for ensuring that all requirements of the MDD are implemented within its quality system. This includes:

- Maintaining an adequate and effective quality system
- Ensuring that all devices meet the requirements of the MDD
- Reporting incidents and near incidents to the Competent Authority
- Registering class I devices, custom-made devices, and procedure packs with the Competent Authority
- Obtaining approval from the Competent Authority before the initiation of most clinical investigations
- Obtaining and maintaining the applicable certifications from the Notified Body before product marketing (except for the devices managed by the Competent Authority)
- Having a European "location" (see the section on "European Representative")

F. European Representative

The MDD requires every manufacturer with a device on the market in the EU to have a registered place of business in a member state. If the manufacturer does not have such a place, the manufacturer should designate a "European Representative." The European Representative has the legal responsibility for registering the manufacturer and the class of devices with the Competent Authority of the member state in which the European Representative is located. Although the MDD does not specify other responsibilities for the European Representative, Notified Bodies usually want to see a contract between the manufacturer and the European Representative. The contract must specify the legal requirement of registration and all applicable optional services (e.g., complaint notification or investigation, MDV reporting, recall, or advisory notice responsibilities).

IV. DOCUMENTATION HIERARCHY

Many regulatory documents are applicable to the medical device manufacturer, and the following hierarchy of requirements exists:

1. National Laws Within Each Member State:

These laws implement the MDD and other Council Directives at the national level. They may also include additional requirements not specified in the Directives, such as local language requirements. Compliance with National laws is mandatory.

2. The Directives:

The Directives have been approved by the Council but have no direct force until they have been implemented by the national laws. Compliance with the Directives is mandatory.

3. MEDical DEVice (MEDDEV) Documents:

These are "guidance" documents designed to promote a common approach by manufacturers and Notified Bodies during the conformity assessment process. They are created by means of a consultation process that includes input from the Competent Authorities and/or Commission Services, Notified Bodies, industry, and other interested parties.

MEDDEV documents are not legally binding, and it is recognized that under some circumstances an alternative approach may be possible or appropriate to comply with the legal requirements. However, because the MEDDEV documents are a consensus agreement on how to interpret the requirements of the MDD, compliance with those documents is usually mandatory. For a link to all MEDDEV documents, visit the following Web site:
http://ec.europa.eu/enterprise/medical_devices/meddev/index.htm

4. Harmonized Standards:

These standards, which were drafted by 1 of 3 European Standard organizations (the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), or the European Telecommunications Standards Institute (ETSI)) that provide technical specifications. Standards are adopted after public input and approval by national voting. Adoption is documented in the Official Journal of the European Union (OJEU).

Products manufactured in conformity with harmonized standards are presumed to conform with the essential requirements. Compliance with harmonized standards is not mandatory because alternate compliance paths are possible; however, the manufacturer has the obligation to prove that its products conform with the essential requirements. Thus compliance with harmonized standards is highly recommended. For a link to harmonized standards, visit the following Web site:
http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html

5. Notified Body Recommendations:

These "guidance" documents are created by a group of Notified Bodies. Although Notified Body recommendations are not as powerful as MEDDEV guidance documents, compliance with them is highly recommended. For a link to Notified Body recommendations, visit the following Web site:
http://www.bsiamericas.com/MedicalDevices/GuidanceDocs/NBRecommendations.xalter

6. Industry Standards:

Industry standards are drafted by Standards organizations (e.g., American Society for Testing Materials (ASTM), International Standards Organization (ISO)) and provide technical specifications. Compliance with industry standards is optional but recommended.

7. Internal Standards:

In the absence of harmonized or industry standards, the manufacturer may create its own internal standards that are based on the clinical requirements of the device. If such standards are created, compliance with their requirements is necessary.

Note: The links provided above are for reference only and may be modified or changed by their owners at any time.

V. THE MDD

A. Overview

The MDD has 3 distinct sections:

- ***The "Whereas":*** This section of the MDD establishes the legal basis for the Articles and Annexes. Compliance is not critical, so review that section after having read the other sections.

- ***The Articles (1-23):*** The Articles define the requirements that must be met to comply with the MDD. The scope of the Articles is very broad and covers items such as definitions, applicability of classification, clinical trials, conformity assessment routes, registration, standards, technical files, vigilance reporting, etc. A thorough review of the Articles and the integration of their requirements into the quality system of the manufacturer is critical to complying with the requirements of the MDD.

- ***The Annexes (I-XII):*** Annex I is absolutely critical. This Annex details the essential requirements (biocompatibility, sterilization, mechanical and/or electrical performance, labeling, clinical data, etc.) that must be met to demonstrate that a device is safe and effective.

ANNEX I DETAILS THE ESSENTIAL REQUIREMENTS THAT MUST BE MET TO DEMONSTRATE THAT A DEVICE IS SAFE AND EFFECTIVE.

Annexes II through VII define the various conformity routes that are available to manufacturers. Those routes are discussed in detail below under the subheading "Conformity Assessment Routes." Annex VIII and Annex X define the requirements for special products (custom devices and devices for clinical investigations). Annex IX defines the rules for classifying devices, which is discussed in detail below under the subheading "Device Classification." Annex XI defines the requirements that the Notified Bodies must meet. This Annex is usually not applicable to the manufacturer, so it is not discussed in detail in this document. Annex XII defines the size and font that must be used in CE marking devices.

B. Definition of "Medical Device"

The MDD provides the following definition of a medical device:

> "Medical device" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software 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.

Thus devices that achieve their purpose via pharmacologic, immunologic, and/or metabolic means are excluded from the definition of a medical device. However, devices that incorporate drugs but do not achieve their primary purpose via the action of the drug (e.g., a fixation pin coated with an antibiotic agent) are regulated by both the MDD and 65/65/EEC.

C. Device Classification—Part 1: Overview

Classification is determined in accordance with Annex IX of the MDD. In addition, the MEDDEV 2.4 provides detailed guidance on classification. Numerous conformity assessment routes are provided by the MDD to demonstrate that a device meets the requirements. The conformity assessment routes that are usually used depend on the risk of the device. The following device classifications exist within the MDD:

- Class I (devices of lowest risk)
- Class I measuring and class I sterile
- Class IIa
- Class IIb
- Class III (devices of highest risk)

Note: The MDD provides numerous conformity assessment routes. This document focuses on the routes most commonly used by industry. For very unusual cases, it may be appropriate to use an alternate assessment route.

Class I Devices

For class I devices, which are those of lowest risk, the MDD requires minimal controls. Although the manufacturer must comply with all requirements of the MDD, a Notified Body is not required or allowed to certify such products. Instead, the manufacturers of class I devices must "self-certify" their devices. Manufacturers of class I devices are not required to have a certified quality system. Furthermore, it is not possible to have a certificate from a Notified Body that covers class I devices. To show compliance with the MDD, class I devices are marked with a "CE."

ALL ASPECTS OF THE CLASS I MEASURING AND CLASS I STERILE DEVICES ARE SELF-CERTIFIED BY THE MANUFACTURER WITH THE EXCEPTION OF THOSE MEASURING FUNCTION AND/OR STERILITY.

Class I Measuring and Class I Sterile Devices

Class I measuring devices and class I sterile devices are the most confusing classes of products, because they incorporate some of the requirements of class I devices and some of the requirements of devices of higher risk.

All aspects of the Class I measuring and Class I sterile devices are self-certified by the manufacturer (see Class I devices) with the exception of those measuring function and/or sterility. For those functions only, the Notified Body must certify Class I measuring and Class I sterile devices. Manufacturers of class I measuring and class I sterile devices must have a certificate from a Notified Body that covers the devices. Typically, this certification is obtained via Annex V of the MDD. Further, the manufacturer needs to have a certified quality system under ISO 13485, Medical Devices—Quality Management Systems—Requirements For Regulatory Purposes.

Note: The certification of the quality system can be limited to cover only the measuring and/or sterilization portion of the device. However, this is not typically done, because most manufacturers have multiple devices, including the higher risk devices described below.

To show compliance with the MDD, class I measuring and class I sterile devices are marked with a "CExxxx" where "xxxx" is the identification number of the Notified Body.

CLASS	RISK	EXAMPLES
Class I	Low Risk	Reusable Surgical Instruments, Sterilization Trays
Class IIa	Low-Medium Risk	Trial Implants
Class IIb	Medium-High Risk	Orthopedic Implants (Trauma, Spine, Small Bone & Joint), Excluding Class III Devices
Class III	High Risk	Total Hips, Total Knees, Total Shoulders, Drug Combinations Devices

Class IIa and Class IIb Devices

Because class IIa and class IIb devices are those of higher risk, all aspects of such devices must be certified by a Notified Body. Manufacturers of class IIa and class IIb devices must have a certificate from a Notified Body that covers those devices. Typically, this certification is obtained via Annex II.3 of the MDD. In addition, the manufacturer must have a certified quality system as specified in ISO 13485. To show compliance with the MDD, class IIa and class IIb devices are marked with a "CExxxx" where "xxxx" is the identification number of the Notified Body.

Class III Devices

Class III devices must meet the requirements of class IIa and/or class IIb devices, as well as three additional requirements. These include: 1) having the actual product certified before its distribution, 2) having major changes reviewed by the Notified Body before implementation, and 3) having to renew the certification on a periodic basis. Manufacturers of class III devices must have a certificate from a Notified Body that covers the devices and the product. Typically, this certification is obtained via Annex II.3 and Annex II.4 of the MDD. Further, the manufacturer must have a certified quality system as specified in ISO 13485. To demonstrate compliance with the MDD, class III devices are marked with a "CExxxx" where "xxxx" is the identification number of the Notified Body.

D. Device Classification—Part 2: Key Aspects That Affect Classification

The classification of a device depends on the duration of use, the invasiveness of the device, the clinical site of use, the connection to a power supply, and other considerations. Those terms are defined in the following list, which also provides information about the various issues that affect classification.

- Duration of use
- Invasiveness
- Clinical site of use
- "Active Device"
- Other considerations

E. Device Classification—Part 3: Common Classifications

For the orthopedic industry, the following classifications usually apply:

- Class I: Reusable surgical instruments, sterilization trays
- Class I measuring: Calipers, rulers used to measure anatomy
- Class IIa: Trial implants
- Class IIb: All implants except for class III devices
- Class III
  - Hip, knee, and shoulder joint replacement devices
  - Bioabsorbable devices
  - Devices with an integrated drug

F. Conformity Assessment Routes

The various conformity assessment routes are defined in Annex II through all of VII of the MDD. Detailed below are the typical conformity assessment routes used in the orthopedic industry by device classification:

- Class I devices
  - Annex VII: Self-declaration by manufacturer
- Class I sterile, class I measuring devices
  - Annex V: Product quality assurance (also requires certification by a Notified Body to ISO 13485)
  - Annex VII: Self-declaration by the manufacturer
- Class IIa and class IIb devices
  - Annex II.3: Full quality system (also requires certification by a Notified Body to ISO 13485)
- Class III devices
  - Annex II.3: Full quality system (also requires certification by a Notified Body to ISO 13485)
  - Annex II.4: Product design, which requires that the product be certified by a Notified Body

Note: The MDD provides numerous conformity assessment routes. This document focuses on the routes most commonly used by industry. For very unusual cases, it may be appropriate to use an alternate assessment route.

ALTHOUGH MOST MANUFACTURERS WILL NOT HAVE MANY MDD-RELATED RECORDS BEFORE THE CERTIFICATION AUDIT, IT IS NECESSARY TO HAVE A TECHNICAL FILE AND/OR DESIGN DOSSIER COMPLETED FOR THE DEVICE(S) THAT ARE BEING CERTIFIED.

VI. CERTIFICATION PROCESS

A. Overview

To become certified by the MDD, the manufacturer must ensure that its quality system is compliant. This typically includes:

- Complying with the ISO 13485:2003 Medical devices—Quality management systems—Requirements for regulatory purposes
- Creating MDD-specific procedures and/or work instructions
- Creating MDD-specific contracts
- Creating records that demonstrate compliance with the procedures

Except for class I devices, the manufacturer must be certified by a Notified Body before CE marking and shipping the devices. This process is described in more detail below.

B. Procedures Required to Implement the MDD

Several procedures and/or work instructions are usually required to implement the requirements of the MDD. In addition, the standard quality system procedures must also link to the various MDD-related documents. Here are some of the MDD-specific procedures that are usually required:

- Technical file and/or design dossier creation and maintenance
- Clinical data
- Medical device vigilance reporting
- Notification of Notified Body
- Compiling a list of CE-marked products
- Label translation and/or verification

C. Contracts Required to Implement the MDD

Contracts are often required when a manufacturer delegates quality system and/or regulatory responsibilities to other firms. Examples of potential contracts include:

- An EU representative contract
- Distributor contract(s)
- Original Equipment Manufacturer (OEM) supplier contract(s)
- Supplier contract(s) with suppliers performing key aspects of the quality system (e.g., design control, contract manufacturing of a finished device, sterile packaging, sterilization)

D. Records Required to Demonstrate Compliance with the MDD

Although most manufacturers will not have many MDD-related records before the certification audit, it is necessary to have a technical file and/or design dossier completed for the device(s) that are being certified. The content of a technical file and a design dossier are very similar or may be identical. The variations in terminology are used to reflect the different class of device: "design dossier" refers to the file created for class III devices, and "technical file" refers to the file created for all other classes of devices.

The technical file contains all items required to demonstrate compliance with the essential requirements. Below is a typical list of items included in or referenced by a technical file and/or design dossier:

- Title of technical file
- Table of contents
- Revision history
- Name and address of manufacturer
- Name and address of EU representative
- List of all manufacturing sites covered by the quality system
- Product description
- Completed essential requirements checklist (ERC)
- List of applicable harmonized and/or industry standards referenced in the file
- Overall manufacturing and inspection plan
- Risk-management documents
- A clinical data report
- Declaration of Conformity (DOC), which is a legal document signed by the manufacturer's senior management
- Labeling
- Other items as required by the Notified Body

VII. TOP SEVEN ERRORS IN IMPLEMENTING THE REQUIREMENTS OF THE MDD

Numerous errors are made by manufacturers that try to implement the requirements of the MDD. Some of the most common errors are:

1. Not Integrating the Requirements of the MDD Within the Quality System
2. Inadequate Technical Files and/or Design Dossiers
3. Inadequate Medical Device Vigilance Reports
4. Shipping Products That Are Not Certified
5. Labeling Errors
6. Device Misclassification
7. Inadequate Subcontractors

VIII. COMPARING REGULATIONS: EUROPE VERSUS THE UNITED STATES

A. Quality System Comparison

The US regulations for medical devices are specified in the Code of Federal Regulations (CFR). One of the most important US regulations is covered in CFR 21.820, Quality System Regulations. This regulation is similar to the ISO 13485 in content, but there are subtle differences that must be considered when a quality system is established.

In the United States, the FDA performs its own compliance audits. The frequency of these audits is determined by the FDA and may vary widely (from annually to more than every five years). The results of the audits are documented in findings ranging from an inspectional observation (FDA-483) to a warning letter. Serious findings are published, and thus competition and customers are aware of important issues that the manufacturer must address. In Europe, the audits are performed by the Notified Body. Audits are conducted annually, and the results of the audits are confidential unless certification is withdrawn.

B. Regulatory Comparison

In Europe, the process for obtaining regulatory clearance to sell products differs greatly from that in the United States, where a regulatory filing is required for most products. This may be a 510(k) claiming substantial equivalence to an existing device or a Premarket Approval for novel products to demonstrate safety and effectiveness. In either case, the FDA must either clear the device for distribution before the product can be used clinically or grant approval through an Investigational Device Exemption process in which the company initiates the clinical study of an investigational device to show its safety and effectiveness.

In Europe, a regulatory filing is required for very few products (primarily class III devices and devices not covered under the scope of a company's existing certification). Thus in Europe, a company that is certified to design, manufacture, and distribute orthopedic fixation devices may distribute the product after completion of the technical file and the Declaration of Conformity without submitting the file to the Notified Body or Competent Authority for approval. Instead of reviewing the technical documentation in advance, the Notified Body will randomly select technical file(s) to review during the next surveillance audit. Thus it is possible that a device may be distributed for many years without any regulatory oversight.

IX. CONCLUSION

In summary, medical device companies who focus to market technologies in Europe must comply with the requirements of the MDD. For most orthopedic companies, this means being certified to ISO 13485 and the MDD by a notified body. Furthermore, the company must have objective evidence that each device it distributes is safe and effective. High risk devices, a separate certification by a notified body is required.

Many companies do not have the experience or resources to properly comply with the MDD. This can be caused by inadequate procedures, lack of adherence to procedures, inadequate or non-existent contracts, or inadequate evidence that a device meets the requirements of the MDD. It is necessary for a company to focus not only on the mechanical function of its device, but also the numerous other aspects of the design including biocompatibility, cleanliness, sterility, packaging, labeling and clinical data. Lack of compliance may result in the inability to distribute, or delay in distribution of devices in the EU and EEA.

The benefits of compliance to the MDD are many. Devices can be distributed to all countries in the EU and EEA, and for most products, no lengthy regulatory review process is required. Further, companies can introduce and/or modify devices quicker than in most other markets. Finally, companies with a certified quality system and MDD certification find that their certifications are a great help when going through the regulatory process in non-European countries.

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About MCRA

MCRA was founded in 2003 and provides "first-in-class" service to its clients through its superior knowledge base, global surgeon relationships and deeply experienced management team. MCRA places particular emphasis on working with companies at all stages of development, whether they are single-product companies or companies with several thousand technologies.