

## Introduction to the CE Mark

**Presented by**

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*Subject Matter Expert, QPharma*

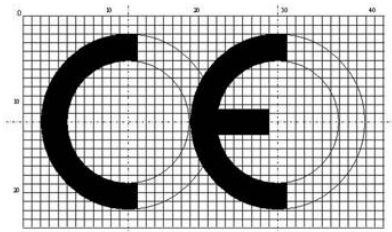
## IN BRIEF

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The “European Conformity” (*Conformité Européenne*) mark is essential for marketing many products in Europe (*especially Medical Devices*).

This presentation explains the types of Medical Devices subject to CE marking and the general requirements for obtaining marketing permission.

CE 0123



## YOUR PRESENTERS

***Deborah Ford*** is a QPharma Regional Manager, located in Bethesda, MD., and responsible for the Midatlantic region.



Deborah has over 20 years experience working in quality in both regulated and non-regulated organizations. She has led numerous projects to put in quality systems in compliance with the Quality System Regulation, ISO 13485, ISO 9001, IVDD, MDD, and CMDR. The quality systems for IVDD and MDD required her to understand and implement products that required the CE mark.

## YOUR PRESENTERS

***Jeff Boatman*** is a Subject Matter Expert on Medical Devices and Quality Systems at QPharma headquarters in Morristown, N.J.

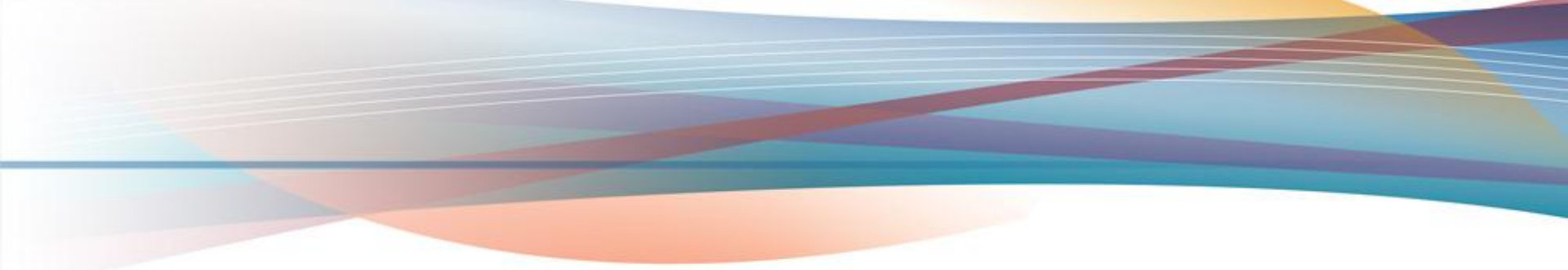


Jeff has 20 years in the Life Sciences industry as a manufacturing, validation, quality, and R&D engineer. A Certified Quality Auditor, he holds several Medical Device patents and teaches Quality Systems through the American Society for Quality. In 1993, Jeff was an R&D Lab Supervisor at Becton Dickinson when EN46001 compliance became a corporate objective, and so was intimately involved with CE marking from the beginning.



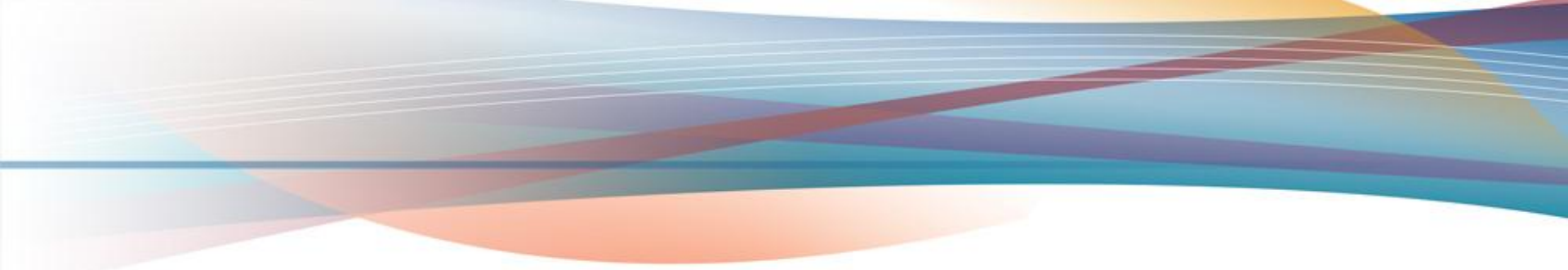
# What is a CE Mark?

**C E**



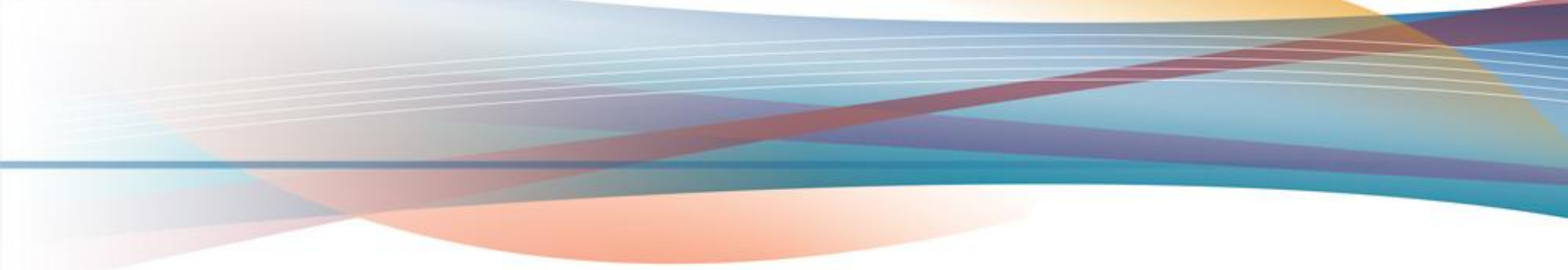
The *Conformité Européenne* mark certifies that a product (and in most cases the quality system that supports its design and manufacture) protects consumer safety by meeting minimum European Union expectations for health, safety, and environmental requirements.





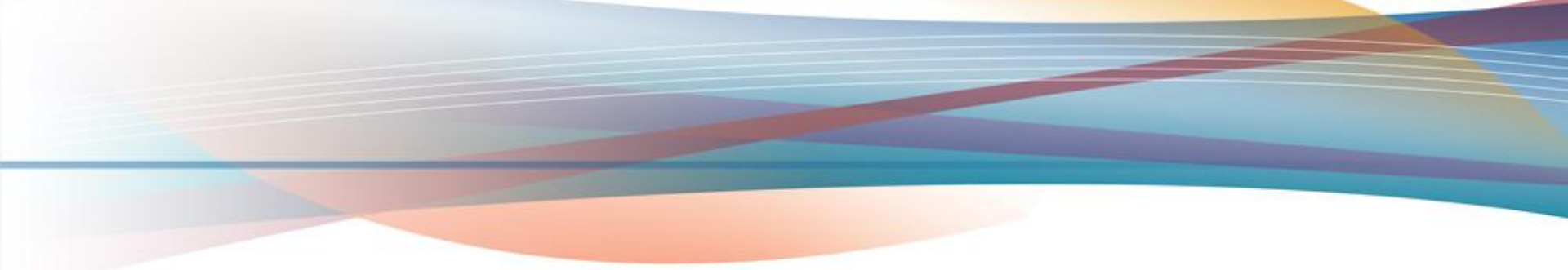
Originally introduced in 1993 (Article 249 of the European Community Treaty) as a voluntary means of ensuring a product met harmonized requirements across EU member states, CE marking is today essentially *mandatory* for the covered product types.

CE marking of Medical Devices skyrocketed in 1998 when both *93/42/EEC* and the U.S. *Quality System Regulation* became mandatory.



On September 21, 2007 Directive 2007/43/EC amended Directive 93/42/EEC on Medical Devices and Directive 90/385/EEC on active implantable Medical Devices. The changes mainly applied to:

- essential requirements
- conformity assessment procedures
- and the classification of devices



Medical devices placed on the market or put into service after March 21, 2010 must be in conformity with the (new) requirements of the revised directives.



Products that have received CE approval bear one of several marks, depending on the type of product:

**CE** “Self-certified”

**CE 0123** “Certified by Notified Body” (with NB code)

**e** “Motor vehicle component”



Products that are subject to CE marking as the result of various European Council Directives include:

- Toys
  - Electrical Equipment
  - Pressure Vessels
  - Elevators
  - Medical Devices *93/42/EEC*
    - Active Implantable Devices *90/385/EEC*
    - *In-vitro* Diagnostic Devices *98/79/EEC*
  - Machinery
  - Gas appliances
  - Scales and balances
  - Protective equipment
- and lots of others, too!*



# **Why do I Want a Medical Device CE Mark?**

For all practical purposes, CE marking is *mandatory* on every product for which a Council Directive exists if you want to market that product in

- The EU: 27 countries...a third of the world's economy...universal
- healthcare...500 million people!



- The EFTA



- The EUTCU



Even when technically *not required* outside the EU, CE marking can be very handy because CE marking is given priority or automatic recognition (e.g. the CEFTA and many countries with Trade Agreements with the EU); while in other cases (e.g. Canada), the local processes required to obtain marketing approval are similar to those for getting a CE mark.





# **How do I Obtain a Medical Device CE Mark?**



First of all, you need to be registered to the ISO 13485:2003 Quality Standard by a *Notified Body* authorized by a *European National Registrar*.

- If you plan to market a Medical Device in Canada (especially if the Device is greater than Class I), you should use a CMDCAS-listed Notified Body.
- U.S. firms that offer “ISO registration” generally are *not* authorized by European governments, carry *no* legal weight, and will *not* result in a CE mark!



Next, you will need to know your device category:

- Class I, IIa, IIb, III (= Class I through IV in Canada)
- IVD, active implantable, “everything else”

This tells you your basic regulatory pathway...

- Which *MDD* applies and the all-important *annex*
  - Self-declared (Class I)
  - Technical File (Class IIa)
  - Design Dossier (Type for Class IIb, Design for Class III)
  - **Gotchas!**

## Designate a *European Authorized Representative*

- Your official presence in the EU
- Local liaison with Competent Medical Authority
- Maintains your records
- Directly equivalent to FDA's *U.S. Agent*
  - Does your company have a European division or branch?  
*Make them your European Representative!*
  - No presence in Europe? *Some EU consulting companies hire themselves out as European Representatives.*

## Class I

Class I manufacturers self-certify and put a “CE” mark on their product, packaging, and marketing materials. A list of Class I devices distributed is filed with the local Medical Competent Authority. The manufacturer publishes a “Certificate of Conformity” as evidence of CE compliance.



## Class IIa

Class IIa devices have to be accompanied by a Technical File and internal verifications (under ISO 13485 design controls). A Notified Body reviews the Technical File and the verification/validation data and issues a Certificate to the manufacturer or distributor, authorizing them to generate a Certificate of Conformity and label the product with the CE mark.



## Class IIb

In addition to a Technical File and internal verifications, the design of a Class IIb device has to undergo a detailed examination of the design inputs and outputs, detailed and traceable review of standards conformance, and other items typically in the U.S. Design History File. The Notified Body will provide a *Type Examination Certificate* and overall you will maintain a “Design Dossier” on the product.

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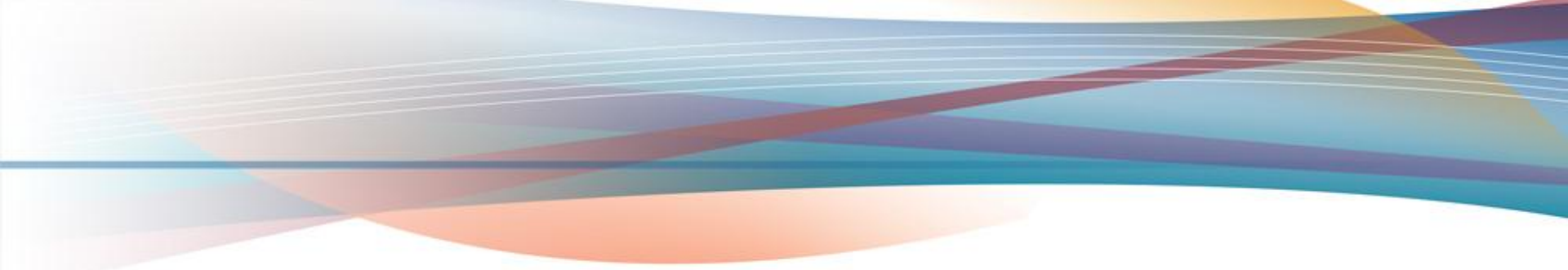
## Class III

In addition to the requirements for a Class IIb, the Notified Body will perform a much more detailed examination of the device, its risk assessments, and applicable standards (a *Design Examination*), similar to FDA's review of a U.S. Premarket Approval application. The Design Dossier for a Class III device is comparable to a PMA in the U.S.

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# **How do I Maintain a Medical Device CE Mark?**



Class I devices may need to be periodically re-listed with the local Competent Medical Authority in accordance with national regulations.

For all other devices, the Notified Body will specify the length of time the CE mark authorization is valid for, at which time an abbreviated recertification process must be undertaken.

- According to 93/42/EEC, this is “not more than five years”
- According to NBOG BPG 2009-4, ongoing surveillance audits must be conducted “for each certification period, and at least every 3 years”
- ISO 17021 requires basic surveillance audits once a year



# **What are the Pitfalls of a CE Mark?**

# Labeling!



In THEORY, a CE mark authorizes you to distribute your product throughout the EU, and no member state can bar you from distribution. To obtain a CE mark, your product labeling must be in *at least* the five primary EU languages.

In PRACTICE, you may need to have SOME or ALL of your labeling in MOST or ALL of the languages officially recognized by the EU.

# Cost!

- Ongoing compliance takes money.
  - Initial and *never-ending* ISO13485 registration and audits
  - Keeping a staff (or EU consultant) for EMA/MCA/NB reporting and to keep tabs on changes to standards  
*But still cheaper than having to report to 25-30 countries!*
- Covigilance takes time and may increase legal exposure
  - You are required to have effective systems for global surveillance and reporting of complaints, recalls, etc.
  - U.S. drug manufacturers already have similar requirements

# Organization!

- U.S. *Design History File* ≠ EU *Technical File/Design Dossier*.
  - Similar in a lot of ways, contain mostly the same data
  - But your procedures and processes will need to change to maintain design control data in both formats
- Change Controls need to account for EU/CE impact
- You must adopt *Global Medical Device Nomenclature*
  - Recently became mandatory
  - Explained in ISO 15225

# Additional Standards!

- Europe has LOTS of standards that may apply
  - ISO, IEC, DIN, and *other EC directives*
  - In the U.S., such standards tend to be *optional*
  - In Europe, such standards tend to be *mandatory*
- And numerous *general directives*, too
  - 92/59/EEC *Product Safety*
  - 85/374/EEC *Product Liability*
  - 93/68/EEC *General CE mark considerations*  
*and lots of others...*

Protective Equipment  
Machinery  
Pressure Vessels  
Electrical Equipment

Environmental...Recycling...Electrical Emissions...Preventive Maintenance...

# Liability!

- Distribution and use of your device
  - “I didn’t think it would be sold there” is no excuse
  - “I didn’t know that country’s requirements” is no excuse
  - “I didn’t know it would be used for that” is no excuse
- Mandatory Covigilance and Reporting
  - You *must* have a system for collecting surveillance data and *acting on it*
  - “Plausible Deniability” is *not an option*

# Q&A

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QPharma web site: [www.qpharmacorp.com](http://www.qpharmacorp.com)

EU Medical Device Directives:

[http://ec.europa.eu/enterprise/sectors/medical-devices/documents/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/medical-devices/documents/index_en.htm)

MDD Guidance Documents:

<http://ec.europa.eu/enterprise/sectors/medical-devices/documents/guidelines/>

MDD Notified Bodies authorized to grant CE mark approvals:

[www.ec.europa.eu/enterprise/newapproach/nando](http://www.ec.europa.eu/enterprise/newapproach/nando)

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Risk management solutions for the medical technology and life sciences industry



Complimentary webinar: "Pharmacovigilance in a Post-Wyeth v. Levine world" - March 24<sup>th</sup> - Register

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Access important products liability risk management information.

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## Webinars & Podcasts

- Podcast Pharmacovigilance in a Post-Wyeth v. Levine World
- FDA Outlook 2010 Webinar
- FDA Outlook for 2010 Podcast

## Publications

- Protecting PMA Devices
- Federal Preemption
- The Basics of Contractual Risk Transfer

## Training Courses

- Sales Reps in the OR
- Writing Defensively
- Warnings and Instructions

## About Medmarc Protect

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### Employee Training

Train your staff to recognize and mitigate products liability risks.

### Integrated Risk Management

Incorporate products liability risk management into your quality management system.

## Latest Tweets

- MedmarcIns: Problems with heparin suppliers have led to nationwide shortages. To reduce supplier risk see <http://tinyurl.com/yctujtr>. #losscontrol #devis
- MedmarcIns: Drug & device execs in FDA's crosshairs. FDA announces it will increase criminal prosecutions <http://tinyurl.com/yfba3mh> #losscontrol #dysan
- MedmarcIns: After 18 recalls of insulin pumps over the past 5 years, the FDA is taking note. <http://tinyurl.com/ybyp12x> #losscontrol #devis

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Ask an Expert

Submit your question related to the medical technology and life sciences industry, concerning:

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- FDA Compliance

Question of the Month

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Medmarc's webinars and podcasts address important issues relevant to the medical technology and life sciences industry. Our 50-minute webinars discuss these issues in depth and our podcasts provide general overviews and brief insights. **Presenters are experts** in the industry and the information provided is designed to educate our policyholders on **preventive products liability practices** and **current industry concerns**.

### UPCOMING WEBINAR

Pharmacovigilance - March 24, 2010 2:30 PM EDT



Genese K. Dopson, JD, is a Partner in the San Francisco office of Wilson Elser Moskowitz Edelman & Dicker LLP. She is a former Oncology Head Nurse and her practice focuses on the defense of pharmaceutical and medical device manufacturers, as well as personal injury and employment discrimination matters. In this webinar, Ms. Dopson recaps the *Wyeth v. Levine* decision and recent state court decisions and discusses how *Wyeth* has impacted—and likely will continue to impact—generic drug manufacturers.

#### FDA Outlook for 2010

- Webinar, Slides
- Podcast (15 minutes)

#### Legislative Outlook for 2010

- Webinar, Slides
- Podcast (20 minutes)

#### Warnings & Instructions

- Webinar, Slides
- Podcast (9 minutes)

#### Managing the Risk of Off-Label Promotion

- Webinar, Slides

#### Non-Manufacturer Sellers of Medical Products

- Webinar, Slides

#### Sales Representatives in the OR

- Webinar, Slides

#### Getting Your Foot in the Door With Medical Device & Life Sciences Companies

- Webinar, Slides

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## THE CE MARK

With the gradual elimination of economic boundaries, more and more U.S. manufacturers will need the "CE" mark on their products in order to market them in Europe. The CE mark indicates that the product **meets the European Union's standards for consumer safety**. These resources contain information on the CE mark, including what it is, how to get it, and how to keep it.

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**Webinar**   
The CE Mark Register  
04/14/2010  
2:30 PM EDT



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**Podcast**   
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### READ



**Risk Management 101**   
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**EU Medical Device Directives**   
  
**MDD Guidance Documents**   
  
**MDD Notified Bodies authorized to grant CE mark**