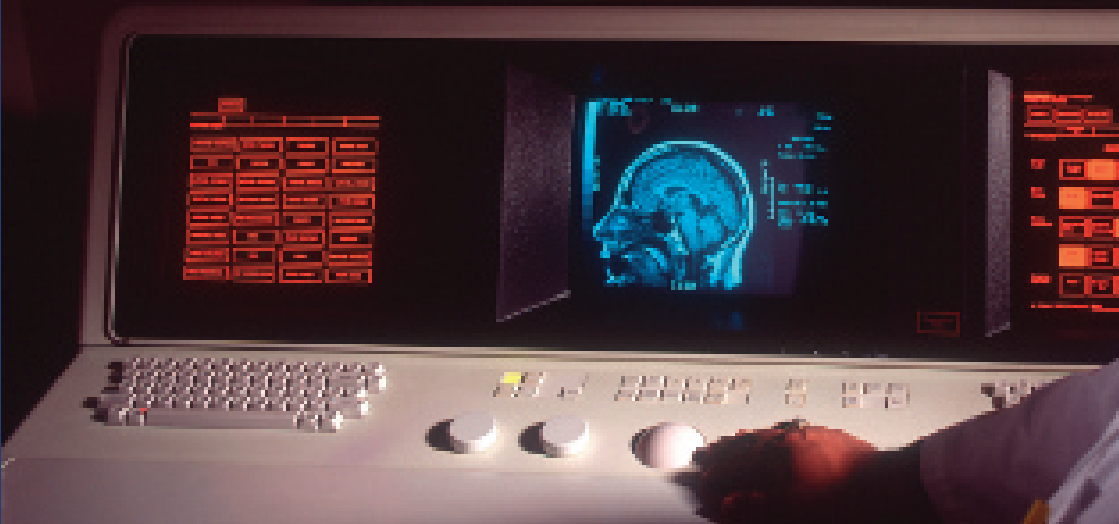


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# DBA



An NSF International Company



## Medical Device CE Marking – The Latest Requirements

Manchester Marriott Victoria & Albert Hotel,  
Manchester, UK

Monday 17 to Wednesday 19 May 2010

# Medical Device CE Marking – The

Manchester Marriott Victoria & Albert Hotel,  
Manchester, UK  
Monday 17 to Wednesday 19 May 2010

## About This Course

The European medical device directives address the methods required in order to place active implantable, general and in-vitro diagnostic medical devices within Europe. Understanding these requirements requires an in-depth knowledge of the regulations, which are often difficult to interpret and apply at an organisational and product level.

This course aims to prepare you with the insights and “quick routes” to understanding, interpreting and applying the requirements and provide you with a clear knowledge of the recent changes to the directives – in particular the amending directive 2007/47.

Even if you have attended medical device CE marking courses in the past this course will bring you up to speed with the latest methods, interpretations and solutions necessary to register and support medical devices in the European market.

## What You Will Learn

- The medical device regulatory (CE marking) framework within the European Union
- The classification system for devices in Europe – what is a medical device?
- The options for CE marking – the different routes you can take
- Interpretation of what type of medical device you have and if it fulfils the description of medical devices including software
- Updates to the medical device CE marking requirements and their impact on you and your products
- The essential safety and performance requirements for medical devices and the solutions used to ensure you meet them
- The documentation required for regulatory submissions to European notified bodies and/or competent authorities and how to stay on top of it
- The links between clinical evaluation, risk management, design, verification and validation and the information for safe use
- Regulatory project management and influencing your organisation – the things you need to know
- Introducing own brand/private labelling
- The role of the authorised representative
- The systems and processes required of a medical device manufacturer, including complaints, adverse events, vigilance and Corrective And Preventive Actions (CAPA) processes

Reserve your place today email: [courses@DBA-global.com](mailto:courses@DBA-global.com)

# e Latest Requirements

## Who Should Attend

- Directors of small companies wishing to place devices onto the European market
- Quality managers or associates who need a better understanding of the medical device CE marking requirements
- Regulatory affairs managers or associates
- Design engineers
- Manufacturing engineers
- Sales and marketing personnel
- Product managers
- Pharmaceutical professionals wishing to learn more about devices

## Your Course Tutors



James Pink  
David Begg Associates, UK



Anne Jury  
David Begg Associates, UK

# Booking Form

## Medical Device CE Marking – The Latest Requirements

**Manchester Marriott Victoria & Albert Hotel,  
Manchester, UK**

Monday 17 to Wednesday 19 May 2010

(Course begins at 09.00 on Monday and closes at 16.00 on Wednesday)

### Course Fee

**First Delegate: £1,000.00 plus VAT**

**Additional Delegate(s): £900.00 plus VAT**

**Includes:** tuition, comprehensive course notes, attendance certificate, lunches, and refreshments

**Excludes:** all hotel accommodation and dinners (see "Accommodation" on The Venue page)

Surname	Mr/Mrs/Miss/Ms/Dr
First Name	Job Title
Company	
Full Street Address	
	Postcode
Delegate Tel No	Delegate Fax No
Delegate Email	

Accommodation: I require accommodation Yes  No

Please indicate any special/extra requirements (dietary/accommodation)

*To guarantee your accommodation reservation, credit card details must be supplied*

Card Number & Expiry Date (please write clearly)

**Course Fees:** Sterling cheques, payable on a UK bank to David Begg Associates (York) Ltd, for the full invoiced amount (net of ALL bank charges) to be attached to this Booking Form and sent to David Begg Associates (York) Ltd at the address below. Settlement must be received at least 10 working days prior to the course start date. A VAT invoice will be provided.  
**VAT Reg. No. GB 927 3679 85.** Under UK law all applications are subject to VAT irrespective of the country of origin of participants. Most VAT registered companies/organisations can reclaim this tax. Cancellations within 25 working days of the course start date are subject to charges (see Cancellations section). If a Purchase Order number is necessary to effect settlement of our invoice please provide it in the box below.

Date	Purchase Order Number
------	-----------------------

Cheque enclosed Yes  No

*To aid prompt confirmation of your booking, please ensure you submit a completed application form which bears an authorised signature and Purchase Order number*

**David Begg Associates (York) Ltd** The Georgian House · 22/24 West End · Kirkbymoorside · York · UK · YO62 6AF  
Tel: +44 (0) 1751 432999 Fax: +44 (0) 1751 432450 Email: courses@DBA-global.com Web: www.DBA-global.com

David Begg Associates (York) Ltd. Registered in England & Wales No. 3432550 Registered Office 22/24 West End, Kirkbymoorside, York YO62 6AF  
An NSF International Company

# Booking your place couldn't be easier!

**Phone** +44 (0) 1751 432999

Our phones are manned between 0900 and 1700 Monday to Friday. Outside these hours you can leave a message and one of our team will return your call as quickly as possible.

**Fax** +44 (0) 1751 432450

You can find further details about DBA and our courses online and either register online or download a booking form and mail or fax it to us.

**Email** [courses@DBA-global.com](mailto:courses@DBA-global.com)

Just drop us an email letting us know which course you are interested in and we will send you full details and a booking form for that course once they are available.

**Online** [www.DBA-global.com](http://www.DBA-global.com)

You can find further details about David Begg Associates and our courses online and download booking forms for any course.

**Post** David Begg Associates (York) Ltd

The Georgian House, 22/24 West End,  
Kirkbymoorside, York, UK, YO62 6AF

## To Book on this Course

- Fax the completed and signed form from this brochure to our Course Administrator. Your place will then be confirmed by post and a course fee invoice will be issued.
- Provisional bookings can be made via our website, in the Training Courses section. Online reservations must be confirmed by the completion of a Booking Form (pdf brochure and Booking Form files can be downloaded via the website).
- Make sure you write a Purchase Order number on the Booking Form if this is necessary for settlement of our invoice.
- Reserve a place by telephone or email (contact details are on the Booking Form) confirming as above.

## Cancellations

Written cancellations with a full refund will be accepted up to 25 working days before the start date of the course. A cancellation fee of 50% will be payable for cancellations received between 10 and 25 working days before the start of the course. If you cancel within 10 working days of the course start date, full course fees will be chargeable. Delegate substitutions may be made at any time up to the start of the course.



# The Venue

However good the training, we know how important the course venue is to you. We realise that a course hotel must be comfortable, easy to get to and back from, offer good service and above all ensure you feel at home.

It is also important to us that our courses are held in high quality professional environments which facilitate hard work and effective learning.

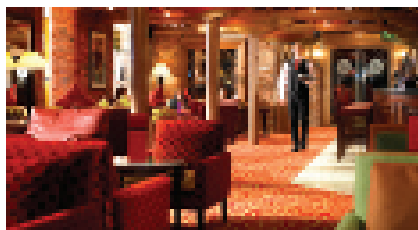
In addition, many provide leisure facilities to aid relaxation at the end of a strenuous day.

## Manchester Marriott Victoria & Albert Hotel, Manchester

Just 20 minutes by cab or train from Manchester Airport, the Victoria & Albert is on the edge of the lively city centre amidst a host of entertainment possibilities. This modern hotel was created from an old warehouse, the character of which is retained with oak beams and exposed brick walls.

### Accommodation.

A specially negotiated bed and breakfast rate of £107.22 plus VAT has been arranged at the Hotel. The nights of Sunday 16 to Tuesday 18 May 2010, will usually be reserved. This should be reserved only through David Begg Associates, using the Booking Form and supplying a credit card detail to guarantee the reservation. Your account should be settled at check out. The hotel reserves the right to make charges against your credit card should you not take up your reservation for any reason. Kindly endeavour to make your accommodation request at least six weeks prior to the course date. Following this date we cannot guarantee bedroom or rate availability.



**Manchester Marriott Victoria & Albert Hotel, Manchester:**

**[http://www.marriott.co.uk/hotels/travel/  
manv-amanchester-marriott-victoria-and-albert-hotel/](http://www.marriott.co.uk/hotels/travel/manv-amanchester-marriott-victoria-and-albert-hotel/)**

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