Title	Compliance with Medical Device Directive 98/42/EEC (MDD)
Description	The course is designed to give you an understanding of the requirements of the Medical Device Directive 93/42/EEC as amended in 2007/47/EC. At the end of the course, you will be able to implement the requirements of the Directive and to audit organizations against it. This course is held in English.
Course Start Date	2015-04-22 09:00
Course End Date	2015-04-24 15:30
Course Location	In Copenhagen. Registration and coffee: 08:45 am to 09:00 am.
Course Content	• Origins of medical device regulation • The role of product and system standard • Quality system requirements • Risk analysis / Risk management • Regulatory structure • The role of Notified Bodies and Competent Authorities • Classification of medical devices • How to select the right conformity assessment route • Design control for existing products • Private Labelling • Technical documentation, design dossiers and DoCs • Clinical evaluation • Labelling and Instructions for Use • Requirements other than those set out in the Directive • Process validation – sterilization as an example • Vigilance • Workshops on relevant subjects to give you practical experience in dealing with the concepts of the course.
Yield	You will be able to confidently advise your colleagues of their roles in compliance with the MDD and to ensure that the relevant documentation is prepared and maintained for scrutiny by your Notified Body. The course will also provide you with important guidance on how to deal with Regulatory Authorities particularly when reporting an adverse incident.
Course Target Group	• Employees who have to implement the provisions of the MDD within their organization • Employees responsible for Quality Assurance and/or Regulatory Affairs • Employees who have to audit organizations against the provisions of the MDD e.g. for the purpose of approving the application of the CE mark to

	medical devices on behalf of Notified Bodies.
Course Teachers	Euan Cameron
Price	DKK 14,850 excl. VAT
Included In Price	The price includes lunch and refreshments as well as material and directive. Excluding accommodation. By simultaneous registration of 3 or more people you will get a 10% discount.
Course Program	**Day 1** 08:45 - 09:00 Registration 09:00 - 09:30 Welcome & Introductions Aims & Objectives of the Course 09:30 - 10:30 Medical Device Directives & Regulatory Systems Harmonized Standards 10:30 - 10:45 Coffee 10:45 - 12:30 Quality System Requirements EN ISO13485:2003 Common Steps to MDD Compliance 12:30 - 13:30 Lunch 13:30 - 14:00 Case Study 1; "What about Class I devices?" (Team Exercise) 14:00 - 14:15 Case Study 1: Report back 14:15 - 14:45 Risk Analysis/Risk Management EN ISO 14971:2007 14:45 - 15:00 Refreshments 15:00 - 16:00 Case Study 2; Risk Analysis (Team Exercise) 16:00 - 16:30 Case Study 2: Report back 16:30 - 17:00 Practical Applications 1 • Regulatory Structures/Competent Authorities & Notified Bodies

Day 2

09:00 - 10:30 Practical Applications 1
• Classification
• Conformity Assessment
• Private/Own-Brand Labelling

10:30 - 10:45 Coffee

10:45 - 12:30 Practical Applications 2
• Essential Requirements
• EC Type Examination
• Technical Documentation
• Declaration of Conformity

12:30 - 13:30 Lunch

13:30 - 14:30 Practical Applications 3
• Clinical Evaluation/Clinical Investigation
• Post-Market Surveillance & Vigilance

14:30 -15:30 Practical Applications 3 (continued)
• Labelling and 'Instructions for Use'
• National Requirements (General)

15:30 - 15:45 Refreshments

15:45 - 16:45 Case Study 3: Clinical Investigation (Team Exercise)

16:45 - 17:00 Case Study 3: Report back

17:00 Close

Day 3

09:00 - 10:15 Process Validation - Sterilization as an Example

10:15 - 11:15 Articles

11:15 - 11:30 Coffee

11:30 - 12:30 Compliance with the Directive (Danish Health and Medicines Authority – Danish National Requirements)

12:30 - 13:15 Lunch

13:15 - 13:30 Review of Course

13:30 - 15:30 Examination (optional)

15:30 End of course

We reserve the right to make changes in the program.

Area of Interest	Medical Devices
Area Of Business	Certification
Contact Person	Sales & Business Support, Presafe Denmark A/S Søren Juul Regnersgaard Tlf.: 3945 4986