



Spring 2010 Deadline

2007/47/EC Provisions and Implementations on Medical Devices

Workshop: May 25th – 26th 2010

IMAM – Rua Loefgreen, 1400 – Vila Mariana, Sao Paulo – SP



“Standards and applications for medical equipment according to the 2007/47/EC”

EROMED is a 2 day workshop exclusively dedicated to the **NEW European Regulation imposed on Medical Devices by the 2007/47/EC**. The Workshop is organized by **Obelis s.a European Authorized Representative Center & GiDoS sprl** in association with **EGMont & Institute for Testing and Certification (ITC)**.

You will be taught by experts in their fields about the latest developments in the European Regulatory framework concerning Medical Devices in reference to the implementation deadline of **March 21st, 2010** by the **2007/47/EC**.

Content by:

Dr. Peter Ruys	Obelis s.a. – Senior Regulatory Expert
Mrs. Sandra Ferretti	Obelis s.a. – Chief Compliance Officer
Mr. Eduardo Monteiro	EG Mont – Chief Executive Officer
Mr. Marcelo Bertochi	EG Mont – Chief Project Officer
Mr. Antonio Carlos Guimarães	Hi-Power, representative of ITC in Brazil

Presentations by:

Mr. Eduardo Monteiro, Mr. Marcelo Bertochi (EGMont) & Mr. Antonio Carlos Guimarães (ITC)

Day 1 – 25th May 2010	
Subjects of the day:	
Attendee's registration including Coffee	8h00 – 8h25
Opening words	8h25 – 8h30
Essential changes in the Medical Device Directive 93/42/EEC by the 2007/47/EC By EGMont (Obelis Senior Expert - Dr. Peter Ruys presentation)	8h30 – 9h00
Notified Body approach to the revision by the 2007/47/EC Mr. Antonio Carlos Guimarães, Hi-Power, representative of ITC in Brazil	9h00 – 9h45
Coffee break	9h45 – 10h00
Technical documentation Mr. Antonio Carlos Guimarães, Hi-Power, representative of ITC in Brazil	10h00 -10h45
Authorized Representative definition, role & duties: comparative analysis By EGMont (Obelis C.C.O – Ms. Sandra Ferretti presentation)	10h45 – 11h45
B2B Meetings	afternoon
Day 2 – 26th May 2010	
Subjects of the day:	
Attendee's registration including Coffee	8h00 – 8h30
EU Member States National Requirements for Medical Devices By EGMont (Obelis C.C.O – Ms. Sandra Ferretti presentation)	8h30 – 9h00
Other European Directives to influence Medical Devices By EGMont (Obelis Senior Expert - Dr. Peter Ruys presentation)	9h00 – 9h45
Coffee break	9h45 – 10h00
2007/47/EC on MDD class I devices – Compliance route to market By EGMont (Obelis C.C.O – Ms. Sandra Ferretti presentation)	10h00 – 10h30
Impact of the Machinery Directive on Medical Devices By EGMont (Obelis Senior Expert - Dr. Peter Ruys presentation)	10h30 – 11h15
Post-market surveillance Mr. Antonio Carlos Guimarães, Hi-Power, representative of ITC in Brazil	11h15 – 12h00
B2B Meetings	afternoon

Participation Fee

	Obelis & EGMont Clients	Non-Clients Before May 5 th	Non-Clients After May 5 th
1 Day	85.00 Reais	180.00 Reais	240.00 Reais
2 Days	120.00 Reais	240.00 Reais	300.00 Reais

Registration

- The registration & payment must be completed with Eduardo Monteiro.
- Forms should be sent by fax or by scanned copy.
- Please note that the number of participants is limited to 80 a day.
- It is highly advised to send in your registration form as soon as possible. Registration will be on a first come, first served basis.

Registration Slip



Registration by Email: contato@egmont.com.br Registration by Fax: 16- 3969 5154

Company Name

Participant 1(Full names, companies, positions)

Participant 2

Participant 3

Total Amount Payable

Deposit to Account: (Check Box) Banco Itaú - ag. 3815 - conta 23163-8 Banco do Brasil - ag. 2172 - conta

Date

Signature

Disclaimer on Cancellation Procedure: Registered participants who cannot attend the workshop may apply for a refund of the "Total Amount Payable" (Above) no later than May 24th. The full amount will be refunded, less a 10 € administrative fee.