



EROMED
European Regulation of Medical devices

Spring 2010 Deadline

2007/47/EC Provisions & Implementations on Medical Devices

Workshop > 20th - 21st October 2009 The Federation of Israeli Chambers of Commerce, 84 Hahashmonaim St., Tel Aviv - Tel: 03/5631023



EROMED is a 2 days 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 **MDC Medical Device Certification GmbH** a German Notified Body, the **Israeli Chamber of Commerce** and the **Israeli Export Institute**.

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 upcoming implementation deadline of **March 21st 2010** by the **2007/47/EC**.

DO NOT MISS OUT THIS YEAR'S SESSION :

"Spring 2010 Deadline: 2007/47/EC provisions and implementations on Medical Devices"

Speakers

Dr. Peter N. Ruys Obelis (O.E.A.R.C) - Senior Regulatory Expert

Dr. Harald Rentschler MDC - General Manager

Mrs. Sandra Ferretti Obelis (O.E.A.R.C) - Chief Compliance Officer (C.C.O)

Dr. Klaus Hogh-Janovsky MDC - Project Leader

Mrs. Daphné Bajkowski Hitter Law Office - Lawyer

Day 1 - Tuesday 20th October 2009

Subjects of the day:

Attendee's registration including Coffee	08h30 – 09h00
Opening words by: Dr. Nadav Sheffer	
Israeli Ministry of Health - Medical Device Department Director	09h00 – 09h15
Essential changes in the Medical Device Directive 93/42/EEC by the 2007/47/EC	
Dr. Peter N. Ruys - Obelis European Authorized Representative Center	09h15 – 09h45
Notified Body approach to the revision by the 2007/47/EC	
Dr. Harald Rentschler - MDC	09h45 – 11h00
Coffee break	11h00 – 11h15
RoHS 2002/95/EC Recast – implications on Medical Devices	
Daphné Bajkowski - Hitter Law Office	11h15 – 12h00
Lunch	12h00 – 12h45
Technical documentation - Dr. Harald Rentschler/Dr. Klaus Hogh-Janovsky - MDC	12h45 – 15h30
Authorized Representative definition, role & duties: comparative analysis	
Mrs. Sandra Ferretti - Obelis European Authorized Representative Center	15h30 – 16h00
B2B Meetings	16h00 – 18h00

Day 2 - Wednesday 21st October 2009

Subjects of the day:

Attendees registration including Coffee	08h30 – 09h00
Clinical evaluation according to the 2007/47/EC	
Dr. Peter N. Ruys - Obelis European Authorized Representative Center	09h00 – 11h15
Coffee break	11h15 – 11h30
EU Member States National Requirements for Medical Devices	
Mrs. Sandra Ferretti - Obelis European Authorized Representative Center	11h30 – 12h00
Lunch	12h00 – 12h45
Other European Directives to influence Medical Devices	
Dr. Peter N. Ruys - Obelis European Authorized Representative Center	12h45 – 13h30
Post-market surveillance - Dr. Klaus Hogh-Janovsky - MDC	13h30 – 14h15
2007/47/EC on MDD class I devices – Compliance route to market	
Mrs. Sandra Ferretti - Obelis European Authorized Representative Center	14h15 – 14h45
Coffee break	14h45 – 15h00
Impact of the Machinery Directive on Medical Devices	
Dr. Peter N. Ruys - Obelis European Authorized Representative Center	15h00 – 15h45
Speaker's summary and conclusions	15h45 – 16h15
B2B Meetings	16h15 – 18h00

Participation fee

	Full price	Members of the Chamber of Commerce & Obelisa	Registration before 15.09.2009	Non members paying before 15.09.09
2 days workshop	1.250,00 ILS	895,00 ILS	720,00 ILS	1.000,00 ILS
1 day workshop	690,00 ILS	495,00 ILS	395,00 ILS	550,00 ILS

Registration

The registration & payment must be completed with the Chamber of Commerce before **October 15th 2009**.

Forms should be sent by fax or by scan copy.

Please note that the number of participants are limited to 55 a day.

It is highly advisable to **send in your registration form as soon as possible**. Registration will be carried out on a **first come first served** basis.

Reply slip



EROMED

European Regulation of Medical devices

Registration by email : college@chamber.org.il Registration by fax : 03-5612614

Company name:.....

Registrant 1.....

Registrant 2.....

Registrant 3.....

full name (as to appear on the given Tag) + company & position

Amount due:.....

For more details and information you may call 03/5631023 or 09/8350983

Payment method: (to mark with an X) Credit card (please call 03/5631023) Check Cash

Date & signature.....

Disclaimer on cancellation procedure: Registration participants who cannot attend the seminar may apply for a refund of the registration fee not later than Thursday, 15th of October 2009. The full amount will be refunded, less a 120,00 ILS administrative charge.