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Australia**



PSB Singapore

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Overview of Electrical Safety to IEC 60601-1 3rd Edition, the New European MDD Directive and Risk Management to ISO 14971

9 April 2008

Novotel Sydney Olympic Park (Room - Freshwater 1)

This full day medical devices seminar will provide participants an overview of the electrical safety testing to IEC 60601-1 3rd Edition, risk management standard according to ISO 14971 2007 version and the update on the new European MDD Directive.

The seminar will cover:

- 1. Morning Session: (speaker Mr Scott Wedesweiler - TCA)**
 - 8.30am – 9.00am:
Arrival & Registration
 - 9.00am – 12.00pm:
60601-1 3rd Ed. Participants will receive up to date information on electrical safety testing to the new IEC 60601-1 3rd Edition, along with implications for design and manufacturing.
 - **12,00pm – 1.00pm: Lunch**
- 2. Afternoon Session: (speaker Mr Paul Tan – TUV SUD PSB)**
 - 1.00pm – 4.30pm:
Risk Management according to ISO 14971:2007. Participants will learn the philosophy of risk management according to ISO 14971.
The new European MDD Directive. Participants will be given an update and general overview of the recently updated European MDD Directive.

Who Should Attend?

- Medical Device Designers, Manufacturers & Distributors
- Regulatory Managers
- Regulatory Consultants

What do participants gain?

- Overview of risk management and its process
- How to comply with the new European MDD regulations
- Overview and safety implications of 3rd Edition of IEC 60601-1
- **All participants receive a certificate of attendance**

About the Speakers:

Mr. Paul Tan – TUV SUD PSB, Singapore

Mr Tan studied electrical & electronic Engineering and obtained a Masters in Business Administration from Hull University, UK. He started his career with the Singapore Government testing laboratories as an Engineer with vast experience in product testing of consumer products such as IT/AV, home appliances, environmental & reliability, medical devices etc.

Presently he is the IECEE CB Lead Auditor in the CB Scheme and also an auditor of active medical devices for TUV SUD PSB Singapore. He leads the TUV SUD PSB NCB (National Certification Body) team for the CB Certification for the TUV SUD Asia Pacific CBTL.

In the IECEE CB Scheme, he is the convenor for the WG15 (Database) and a member in the Risk Management Task Force for Medical Devices.

Mr. Scott Wedesweiler – Testing & Certification Australia, Sydney

Mr Wedesweiler has 15 years extensive experience in electromedical testing and is a NATA signatory.

He is a Member of Society for Medical & Biomedical Engineering (SMBE) NSW Inc. and also a Member of Standards Australia Committees HE-003 (Medical Electrical Equipment), HE-027 (Hospital Beds) & HE-027-00-01 (Paediatric Hospital Beds).

Mr Wedesweiler has had vast experience in product testing of a broad range of electromedical equipment.

**Please see attached Registration form
for further details. Numbers are limited
so register now.**

RSVP no later than 29th March 2008

**Refresh Break , Lunch - Gourmet Working Lunch Buffet
& Recharge Break will be provided**

Registration Form

Seminar Details

IEC 60601-1 Safety Testing, Risk Management to ISO 14971 & The New European MDD Directive

Applicant Details

Title: _____
First Name: _____
Surname: _____
Company: _____
Position: _____
Street Address: _____
State: _____ Postcode: _____
Postal Address: _____
(if applicable)
Phone: _____ Mobile: _____ Fax: _____
Email: _____

Seminar Fees for 9th April

Single: \$AU385 (incl GST) **OR** Two or more: \$AU330/per person (incl GST) †
 Limit 5 per company

Payment Details

Card Type Visa MasterCard Expiry Date /

Credit Card No:

Total amount due \$

Cardholder's name _____

Signature of Card Holder _____ CCV _ _ _

OR

Pay by bank transfer in AUD to
EnergyAustralia Trading Account
Commonwealth Bank of Australia
BSB: 062-815 Account Number: 0000 0270

Please include "med seminar" and
your name in the reference when
transferring your payment

Cancellations

- Please advise us in writing prior to the Seminar should you wish to cancel.
- Cancellations received after 2nd April will incur a 20% cancellation fee.
- Cancellations within 48 hrs of the Seminar will be non-refundable.
- TCA reserves the right to cancel Seminars due to insufficient registrations or conditions beyond its control.
- Applicant will be held responsible for their own travel and or accommodation costs.

Note

- We will consider late registrations based on availability.
- If the registered applicant is unable to attend, please inform us in writing of the replacement candidate.
- Fee includes refreshments, lunches, seminar materials and **attendance certificate**.

† To qualify for \$AU330 (incl. GST) all applicants must be from the same company.

Deadline for registration is due by 29th March 2008.

We will consider late registrations based on availability

If you have any Questions please contact Sue Escott on 02-94105138 or

email sescott@energy.com.au

RETURN COMPLETED FORM TO FAX (02) 9415 1567

2nd Applicant Details

Title: _____
First Name: _____
Surname: _____
Position: _____
Street Address: _____
State: _____ Postcode: _____
Phone: _____ Mobile: _____ Fax: _____
Email: _____

3rd Applicant Details

Title: _____
First Name: _____
Surname: _____
Position: _____
Street Address: _____
State: _____ Postcode: _____
Phone: _____ Mobile: _____ Fax: _____
Email: _____

4th Applicant Details

Title: _____
First Name: _____
Surname: _____
Position: _____
Street Address: _____
State: _____ Postcode: _____
Phone: _____ Mobile: _____ Fax: _____
Email: _____

5th Applicant Details

Title: _____
First Name: _____
Surname: _____
Position: _____
Street Address: _____
State: _____ Postcode: _____
Phone: _____ Mobile: _____ Fax: _____
Email: _____