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Update on Regulatory Requirements for Electrical Medical Equipment (ME).

Tuesday Oct 9th 2018
At Hermon Labs, Binyamina

The medical industry is rapidly adopting new technology that enables better communication and performance of products & systems to improve the quality and availability of care. Manufacturers face a number of compliance challenges, as medically used devices they develop incorporate components and modules that do not meet the medical grade quality and safety standards. As a result, end-use devices present a risk of injury, recalls, bans and liability.

The transition to IEC 60601-1 3rd introduced the concept and application of risk management according to the environments of intended use as well as various classification systems. It is imperative for everyone involved with product design to fully understand how the process of risk management and risk analysis incorporates with new requirements to achieve compliance.

This Medical Compliance Seminar will provide critical insights into technical requirements, the standardization process, the development of IEC 60601-1- family, steps the manufacturer must perform to fulfill risk management requirements to mitigate device malfunction.

WHO SHOULD ATTEND: HW engineers and Regulatory officers.

AGENDA

08:45-09:00 – Gathering, coffee & pastries

09:00-10:45 – Overview of differences between new EU Medical Device Regulation and old MDD

- Changes in Risk Assessment process
- Changes in construction and testing requirements

10:45-11:00 – Coffee break

11:00-12:45 – Use of commercial grade components and subassemblies in ME

- Special safety concerns related to Medical Devices
- Intended use, Essential Performance and Manufacturer responsibilities
- Construction, performance, manufacture and continuous compliance




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12:45-13:45 – Lunch break

13:45-15:15 – Medical equipment EMC requirements – Collateral standard IEC 60601-1-2 Edition 4

- Risk Management with respect to EMC phenomena
- Installation environment and equipment classification
- Technical requirements
- Marking and documents
- Comparison vs Edition 3

15:15-15:30 – Coffee break

15:30-16:15 – Medical products packaging validation

Description and comparison between:

- ASTM standards
- IEC transportation standards

Issues raised by customers and test laboratory for a correct and efficient validation (FAQ)

16:15-16:45 – Update in methods and standards

- ASTM D4169-09 Vibration changes
- IEC/EN 60601-1-12:2015 changes (from previous edition)

16:45-17:00 – Aging for medical products

- Aging per ASTM F1980
- Accelerated life test methods (HALT)

Environmental Lab tour

PARTICIPATION COST IS 280 NIS (INCLUDING VAT).

FOR REGISTRATION PLEASE CLICK HERE

For any questions please send Email to maya@hermonlabs.com, or call 04-6268401\4.




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