

CE Workshop for Medical Devices

Vancouver - September 13, 2010
Morris J. Wosk Centre for Dialogue, Strategy Room

8:00 - 8:30	Registration and continental breakfast
8:30 - 9:00	Welcoming remarks Presentation TÜV NORD
9:00 - 9:45	Overall description of the "European Global Approach" – Legal framework and basic requirements
9:45 - 10:00	Coffee break
10:00 - 11:30	Description of the different conformity assessment procedures (Modular System) – Classification system – Certification process
11:30 -12:00	Special requirements of Medical Devices Directive – Labelling – Instructions for use
12:00 - 1:00	Lunch
1:00 - 1:45	Special requirements of Medical Devices Directive – Technical documentation (incl. Clinical investigation/Risk management, etc.)
1:45 - 2:45	Changes in Medical Devices Directive due to directive 2007/47/EC which is implemented in MDD and came into force in March 2010
2:45 - 3:00	Break
3:00 - 3:30	Outsourcing of Processes – Subcontracting, OEM/Private labelling
3:30 - 4:15	Case studies / Workshop – Practical exercises on real medical devices (classification and certification)
4:15 - 5:00	Workshop conclusion – One-on-One sessions