Announcement

Subject: Invitation to 2-days Industry Awareness Programme on "Understanding EC Regulations and CE Marking and ICMED Certification for Medical Device Manufacturers" on 28 - 29 June 2017 at Andhra Pradesh MedTech Zone Limited (AMTZ), Hill No. 2, IT Park, Madhurwada, Distt. Visakhapatnam - 530045, Andhra Pradesh.

The EU regulatory framework in the Medical device sector comprises Directive 93/42/EEC on Medical Devices, Directive 98/79/EC on in Vitro Diagnostics and finally Directive 90/385/EEC on active implantable (i.e. pacemakers).This framework was under review and the new principles which will apply from 2018 after a three years transitional period and will comprise two Regulations instead of three Directives where relevant provisions regarding the Notified Bodies was set up in Regulation N0 920/2013 of September 2013 and provisions regarding the Authorised Representative (for products entering into the EU from third countries) were appropriately amended.

In the Indian context, Directive 93/42/EEC on Medical Devices covers 85% of Indian manufacturers while Directive 98/79/EC in vitro diagnostics covers 12% and Directive 90/385/EEC on active implantable only the 3% of the Indian manufacturers

In order to facilitate the CE Mark for export purposes in medical devices in the country and provide training to the industry on achieving compliance to EC regulations for CE marking and for capacity building for ICMED Certification a 2-days Programme has been planned on **28 - 29 June at Visakhapatnam** with the financial support from the **Andhra Pradesh Medical Tech Zone (AMTZ)** and in partnership with the **Association of Indian Medical Device Industry (AIMED)** and **World Health Organization (WHO)**.

We invite participants from interested manufacturing industry, medical devices professionals and other stakeholders to register to participate in this 2 days programme.

Please note that this 2-days Industry awareness programme has limited seats and registration will be done on first come first serve basis.

Last date for registration is 26th June 2017

Please confirm your nomination by submitting filled-in registration form as per the nomination form attached by **26th June 2017** to **Ms. Ajita Srivastava** (ajita@qcin.org).

- Registration is Free.
- Registration will be done on First-come-first-serve basis.

For any information, please contact **Ms. Ajita Srivastava**, Contact No. +91 – 11-2337 8056/57, Fax- +91 – 11-2337 8678, email: ajita@qcin.org

2-days Industry Awareness Programme on "Understanding EC Regulations and CE Marking and ICMED Certification for Medical Device Manufacturers"

Venue: Andhra Pradesh MedTech Zone Limited (AMTZ), Hill No. 2, IT Park, Madhurwada, Distt. **Visakhapatnam** - 530045, Andhra Pradesh

On 28 - 29 June 2017

Please complete and return this form **on or before 26th June 2017**
By email or fax* to
Ms. Ajita Srivastava
QCI Secretariat

Email: ajita@qcin.org, **Tel**: +91-11-23378056/57; **Fax** +91-11-23378678
*Sending by email is preferable. Please print clearly if sending by fax

NOMINATION FORM

A. PERSONAL PARITCULARS

Title *(please tick)*	Mr. ☐	Mrs. ☐	Ms. ☐	Dr. ☐

Name	:			
Organization	:			
Position / Designation	:			
Organization Address	:			
City			Postal Code / Zip	
State			Telephone (O)	
Fax			Telephone (R)	
Email Address			Mobile	

Note:

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