

Notification

Number: BIRAC/TG/2018/Regulatory-FTS

Date: 03 Aug 2018

Facilitation for Testing and Standardisation of Medical Devices

BIRAC has collaborated with Kalam Institute of Health Technology, KIHT to facilitate Start-ups, Entrepreneurs, Researchers, Academicians, Incubation Centres, SMEs etc in **Testing and Standardisation of Medical Devices**.

KIHT has empanelled a set of Laboratories which helps in testing to comply with applicable standards like

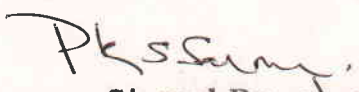
- Electromagnetic Interference (IEC 60601 series)
- Electromagnetic Compatibility (IEC 60601-1-2 series)
- Electrical safety testing
- Biocompatibility (ISO 10993)
- Good Manufacturing Practices (ISO 13485)
- Software testing (IEC 62304)
- Material testing (Relevant ASTM Standards)
- Radiation protection (IEC 60601-1-3)

In addition Rapid Prototyping, Health technology Assessment services are also available. If required, start-ups may also apply for voluntary NIPUN certificate.

The cost of tests varies depending on parameters, duration of testing, testing chamber configurations and number of units required to be tested. **The testing charges are subsidised for BIRAC referred Start-ups to an extent of 40%-70%.**

For further details please click here.

For getting reference through BIRAC and availing the subsidised cost, e-request may be sent to **Sonia Gandhi**, Senior Manager – Investments, BIRAC at sgandhi.birac@nic.in.


Signed By 03/08/18

Dr. P K S Sarma
GM & Head (Technical)