

Indian Certification of Medical Devices (ICMED) Plus Scheme

June 21, 2021

In news

The Quality Council of India (QCI) launched the Indian Certification of Medical Devices (ICMED) Plus Scheme recently

About ICMD scheme

- **QCI** and the **Association of Indian Medical Device Industry** (AiMeD) have added further features to the ICMED, the Scheme that had been launched for Certification of Medical Devices in 2016.
- The ICMED 13485 PLUS, as the new scheme has been christened, **will undertake verification of the quality, safety and efficacy of medical devices.**
- ICMED Plus has been **designed to integrate the Quality Management System components** and product related quality validation processes through **witness testing of products** with reference to the defined product standards and specifications.
- This is the first scheme around the world in which quality management systems along with product certification standards are integrated with regulatory requirements.
- This scheme will be **an end to end quality assurance scheme** for the medical devices sector in India.
- This scheme **provides the much-needed institutional mechanism** for assuring the product quality and safety.
- It will go a long way in assisting the procurement agencies to **tackle the challenges relating to the menace of counterfeit products and fake certification.**

- This will also help in **eliminating the circulation and use of sub-standard medical products** or devices of doubtful origin that could prove to be serious health hazards.

Association of Indian Medical Device Industry(AiMeD)

- AiMeD is an Umbrella Association of Indian Manufacturers of Medical Devices covering all types of Medical Devices including Consumables, Disposables, Equipments, Instruments, Electronics, Diagnostics and Implants.
- The aim behind forming AiMeD is to allow the Indian Government to access a single point of contact and provide various services to the manufacturers like Advocacy on policy issues, Information services, Regulations for Medical Devices etc.
- AiMeD ensures convergence at a one common platform, when needed, for ensuring overall growth of Indian Medical Devices Industry and further address the needs of all members of the Medical Device Industry irrespective of their affiliation or their company size.