



## Medical Devices Testing

- BTH is equipped with walk-in-chambers for all kind of Environmental & Climatic test.
- BTH is also registered by Central Drugs Standard Control Organization (CDSCO).



TC-13278

# BHARAT TEST HOUSE Pvt. Ltd.

NABL ACCREDITED & BIS RECOGNISED, ISO 9001, ISO 14001 & ISO 45001 CERTIFIED LAB



Recognised



## Medical Devices Testing



**Medical equipments:** have penetrated in all walks of life where they have replaced the conventional and old designed/bulky devices with the most sophisticated, highly sensitive compact & digital ones. Therefore their safe operation is also a major concern where for such equipments, there is no compromise on Safety and Durability since the devices are operated continuously for hours and days. Hence looking into the requirements in India, BTHPL has introduced the test facility to conduct Key Safety Test on **Medical Devices** where recommended tests as per National and International standards have been defined.

**BTH** is Electrical safety testing in general is essential to ensure safe operating functions for any product that uses electrical power. Various governments and other agencies have developed stringent requirements for electrical products that are sold across the world. In most of the countries, it is mandatory for a medical devices operated on electricity to conform to safety standards implemented by regulatory agencies. To conform to such standards, the product must pass safety parameters. The current scope of Safety Testing in BTHPL includes **Input Power; Marking & Instructions; Determination of Accessible Parts; Potential Equalization; Surface Coating; Protective Earthing; Functional Earthing; Leakage Current & Patient's Auxiliary Current; Plugs & Sockets; Resistance to Environmental Stress; Dielectric-**

**Strength; Accessible Parts including Applied Part; Functional Earth Terminals; Creepage Distances & Air Clearance; Overflow, Spillage, Leakage Ingress of Water on Particular Matter, Cleaning, Disinfection, Sterilization and Compatibility with Substances used with ME Equipments.**

**MOU: CSIR-Central Scientific Instruments Organisation** and BTHPL have formally joined hands for **Testing & Calibration** of Medical & Bio-medical instruments like Defibrillator, Electrical Safety Test, Electro Surgical Device, ECG, X-Ray Unit, Patient Monitoring System, Ultrasonic-Therapy Unit, Photo-Therapy Unit, Infant Incubator, Pulse Oximeter, NIBP Monitoring System

### Product Category & Related Standard

IEC 60601-1, IS 13450-1,  
IEC 60601-2-41, IEC 60601-2-46

Testing of Medical Electrical Equipment: Surgical Luminaries & Luminaries for Diagnosis, Operating Tables etc.

IS 13450-2-19/IEC 60601-2-19,  
IS 13450-2-5/IEC 60601-2-5,  
IS 13450-2-49/IEC 60601-2-49,  
IS 13450-2-4/IEC 60601-2-4,  
IS 13450-2-21/IEC 60601-2-21

Medical Electrical Equipment: Baby Incubator and Ultrasonic Physiotherapy Equipment

IEC 60601-1, IS 13450-1,  
IEC 60601-2-41, IEC 60601-2-46

Testing of Medical Electrical Equipment: Baby Incubator & Ultrasonic Physiotherapy Equipment

IS 13450-2-19/IEC 60601-2-19,  
IS 13450-2-5/IEC 60601-2-5,  
IS 13450-2-49/IEC 60601-2-49,  
IS 13450-2-4/IEC 60601-2-4,  
IS 13450-2-21/IEC 60601-2-21

Medical Electrical Equipment –Surgical Luminaries and Luminaries for Diagnosis, Operating Tables

### WE OFFER SINGLE WINDOW SERVICE

**Lab 1:**  
781, HSIIDC,  
Industrial Estate,  
Rai, Distt. Sonipat,  
Haryana-131029.



**Lab 2:**  
1474, HSIIDC,  
Industrial Estate,  
Rai, Distt. Sonipat,  
Haryana-131029.

**Lab 3:**  
1668, HSIIDC,  
Industrial Estate,  
Rai, Distt. Sonipat,  
Haryana-131029.

**Lab 4:**  
1668 (DIV-II), HSIIDC,  
Industrial Estate,  
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