

**Regulatory Testing Services**  
**DEKRA Testing and Certification Inc.**  
Sterling, Virginia, USA



A safe world



# Medical Industry- Services

DEKRA TC (USA) provides testing and certification services focused to fulfill the medical industry testing requirement for most of the components to be part of a medical environment.

## According to the IEC/EN 60601-1-2 Medical Electrical Equipment

Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.



# IEC 60601- Series of Standards: Structure

IEC 60601-1 Medical Electrical Equipment

**Part 1: General requirements for basic safety and essential performance**

**IEC 60601-1-X  
Collateral Standards  
(for classes of  
products)**

-1-2: Electromagnetic Compatibility

-1-3: Radiation Protection

-1-6: Usability

-1-8: Alarms

-1-9: Environment

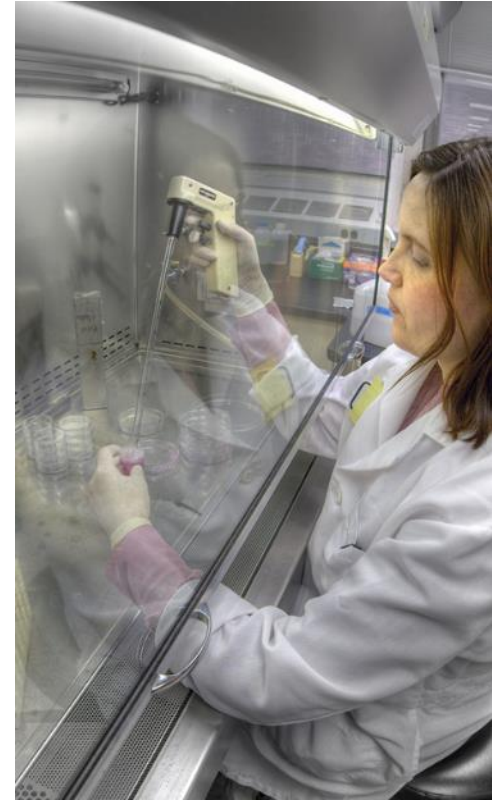
-1-10: Physiological Closed-Loop Controllers

-1-11: Home Healthcare Environment

-1-12: Emergency Medical Services Environment

**IEC 60601-2-X  
Particular Standards  
(for specific products)**

**Part 2: Particular requirements for basic safety and essential performance...of about 70 product families e.g. CT, MR, endoscopic, ultrasonic equipment**



# IEC 60601-1-2: Risk Management Process

## IEC 60601-1: Basic Safety and Essential Performance

