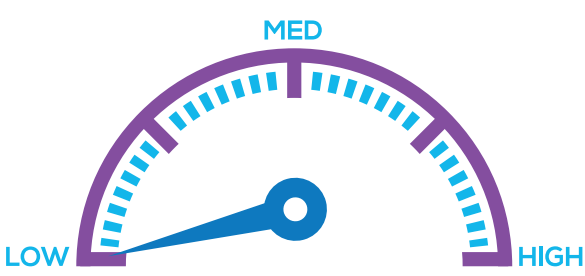


A HANDY GUIDE TO  
**MEDICAL DEVICE**  
CLASSIFICATION

**CLASS I**

**RISK ASSESSMENT:**

Considered low-risk and present the least potential for harm



**CLINICAL TRIAL REQUIRED?**

**NO**

**EXAMPLES OF CLASS I DEVICES:**

bandages, stethoscopes and surgical masks



**CLASS II**

**RISK ASSESSMENT:**

Higher risk than Class I devices. Necessitate stricter regulatory controls to confirm the safety and efficacy of the device

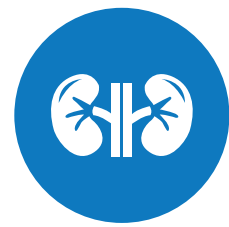
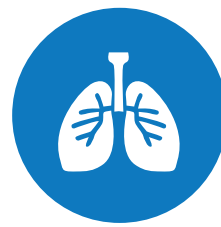
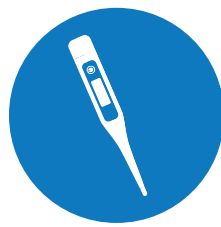


**CLINICAL TRIAL REQUIRED?**

**POSSIBLY**

**EXAMPLES OF CLASS II DEVICES:**

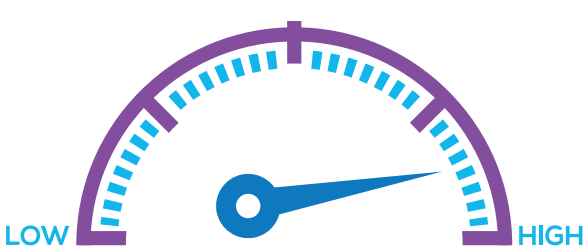
electronic thermometer, intubation sets and urinary catheters



**CLASS III**

**RISK ASSESSMENT:**

Devices either support or sustain life or present an unreasonable risk of injury to the user. Subject to highest level of regulatory control.



**CLINICAL TRIAL REQUIRED?**

**YES**

**EXAMPLES OF CLASS III DEVICES:**

external defibrillators, coronary stents

