



Medical devices classification

Based on the risks associated with; medical devices are classified into one of three categories.

Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. **Class II** devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. **Class III** devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control (*Reference: US FDA*).

Technology Readiness Level

Technology Readiness Level is a measurement system used to assess the maturity of a technology. Each Technology Readiness Level (TRL) has defined characteristics as described below. This gives an indication as to the further work involved in the development of the technology.

With regard to medical device development at BMT Wing the following are the Technology Readiness levels identified

TECHNOLOGY READINESS LEVELS (TRL) : BMT Wing

