

## **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

TRL 1	<ul> <li>Research Idea</li> <li>Shows promising potential application</li> </ul>	CONCEPT
TRL 2	<ul> <li>Applied Research Idea</li> <li>Hypothesis testing and initial proof of concept is demonstrated in a limited number of in vitro / in vivo trials</li> </ul>	
TRL 3	Project plan     Device Characteristics Document & Project proposal completed     Ready for Phase I – Proof of Concept (PoC) Phase	
TRL 4	Development     PoC and safety of the device is demonstrated in in vitro / ex-vivo / in vivo conditions	PROOF OF
	oundono	CONCEPT PHASE
TRL 5	<ul> <li>Standardisation</li> <li>Documentation on design transfer, material evaluation matrix and device evaluation matrix completed</li> <li>Ready for Phase II – Preclinical Evaluation (PCE) Phase</li> </ul>	
	Preclinical evaluation     Preclinical evaluation completed	PRECLINICAL
TRL 6	<ul> <li>Documentation on Device Master File, Technical Advisory Committee / Ethics Committee, Clinician's Brochure and Clinical Trials Protocol Completed</li> <li>Ready for Transfer of Technology (ToT) Phase</li> </ul>	EVALUATION PHASE
	Technology Transfer     Training for the second secon	TECHNOLOGY
TRL 7	Training of Industry / Technology transfer completed     Technology transfer documentation completed     Ready for Multicentre Clinical Evaluation (MCE) Phase	TRANSFER PHASE
	Clinical evaluation	CLINICAL
TRL 8	Clinical Evaluation Completed     Documentation on Device History File completed	EVALUATION PHASE
	Commercialization	COMMERCIALIZATION
TRL 9	Commercialization & Post market surveillance	DUACE
		PHASE