	Frequently Asked Question				
Ref: FAQ:019:01	**RE: Medical Devices Risk Assessment**				
Issue date:	May 2018	**Revised Date:**	October 2020	**Review date:**	October 2022
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Note:	*This information/advice has been issued in response to frequently asked questions around a specific topic and may not cover all issues arising, should you require more specific advice please contact the Health & Safety Help Desk. The management of any occupational safety and health issue(s) remains the responsibility of local management.*				

Does the HSE have a Medical Devices Policy?

Yes, The Medical Devices/Equipment Management Policy, 2009 (Incorporating the Medical Devices Management Standard - 2.1 Statement of Standard) states:

"There is a system in place which ensures that all risks associated with acquisition and use of Medical Devices and Equipment are minimised."

Does Health and Safety Legislation require the risk assessment of medical devices?

Yes, if the device is an article or equipment for *use at work* (i.e. work equipment) then health and safety law applies and the full spectrum of risks (and legal stipulations) must be considered in accordance with the Safety, Health and Welfare at Work Act, 2005. Section 8(1) of the Act states:

"Every employer shall ensure, so far as is reasonably practicable, the safety, health and welfare at work of his or her employees"

Section 8(2Ciii)) extends this duty to:

"the design, provision and maintenance of plant and machinery or any other articles that are safe and without risk to health"

In addition, The Safety Health and Welfare at Work (General Application) Regulations 2007 (as amended) Part 2 Chapter 2 Regulation 28(a) states:

"An employer shall ensure that any work equipment provided for use by employees at a place of work complies, as appropriate, with the provisions of any relevant enactment implementing any relevant Directive of the European Communities relating to work equipment with respect to safety and health"

Examples of such equipment could include a patient hoist, a scalpel or syringe.

Regulation 28(d) states that:

"where it is not possible fully to ensure that work equipment can be used by employees without risk to their safety or health, appropriate measures are taken to minimise any such risk"

Who is responsible for completing the risk assessment?

The completion of the risk assessment is the responsibility of the risk owner (relevant manager) who should be supported by a multi-disciplinary team that may include representatives from procurement and/or a medical device specialist.

What should be considered in the risk assessment?

All aspects of the lifecycle of the medical device/equipment, from the decision to adopt a particular type or piece of equipment to disposal, including what safe systems of work will be required and appropriate location, in essence a cradle to grave risk assessment approach.

Do all medical devices require health and safety risk assessment?

Health and safety legislation does not apply in relation to devices that are provided for patient medical care and are not articles (work equipment) for use or operation by persons at work (at a workplace), for example Dressings and Endoscopes.

However, under the Health Acts and related legislation, civil law, professional codes of conduct and the HSE's internal risk management processes require a duty of care to our patients and it is incumbent on the responsible person (managers and clinicians) to act reasonably and ensure that persons are not placed under foreseeable risk.

A risk assessment by the relevant manager and clinical/nursing/medical lead (as per QAV risk assessment system) and a robust procurement process would ensure the reduction of risk.

How do we identify safe devices?

A device can only be sold/ used in Ireland if the device has been licensed by an EU competent authority such as the Health Products Regulatory Authority (HPRA) which provides its CE mark. The CE mark provides assurance that the device is fit for purpose for which it was intended/ designed.

The device will then be classified further as per Table 1 below for more information please refer to Classification of a Medical Device.

Table 1: Classification of a Medical Device

Class	Type
I	Low Risk
IIa	Medium Risk
IIb	Higher Risk
III	Highest Risk

Additional Information:

Health Products Regulatory Authority HPRA www.hpra.ie