Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2014-2015, 22 October 2014

Ref No: SQ14-001338

OUTCOME: 7 - Health Infrastructure, Regulation, Safety and Quality

Topic: Medical Device Reforms

Type of Question: Written Question on Notice

Senator: McLucas, Jan

Question:

Prof. Skerritt informed the committee that are there four classifications of devices, including several sub-classifications. (a) what exactly each of the classifications and sub-classifications are; (b) what are the examples of each type of device that fits into each category and sub-category; (c) Which classifications and sub-classifications of devices will be accepted via EU risk assessments?

Answer:

The table below outlines the classification structure for medical devices, including risk levels, example products and the conformity assessment requirements for each classification and sub-classification.

Classification	Risk	Examples	Conformity assessment
Class I	Low risk	Surgical retractors, tongue depressors	Self-assessment and certification by the manufacturer according to stipulated criteria
Class I – incorporating a measuring function	Low-medium risk	Thermometer	Conformity assessment certification from either TGA or EU notified body
Class I – supplied sterile		Sterile bandages	Conformity assessment certification from either TGA or EU notified body
Class IIa – non-sterile		Suction unit	Conformity assessment certification from either TGA or EU notified body
Class IIa – sterile		Hypodermic needles	Conformity assessment certification from either TGA or EU notified body
Class IIb	Medium-high risk	Lung ventilator, spine implants	Conformity assessment certification from either TGA or EU notified body
Class III	High risk	Heart valves, hip, knee and shoulder joint implants	Conformity assessment certification from either TGA or EU notified body EXCEPTION: where the product contains medicines or tissues of animal, biological or microbial origin, conformity assessment certification by TGA is required.
AIMD (Active Implantable Medical Devices)		Implantable defibrillator	