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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS
(MEDICAL DEVICES) (AMENDMENT NO. 5)
REGULATIONS 2012

In exercise of the powers conferred by sections 71(1) and 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Health Products (Medical Devices) (Amendment No. 5) Regulations 2012 and shall come into operation on 1st January 2013.

Amendment of regulation 26

2. Regulation 26 of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) is amended —

(*a*) by inserting, immediately after the words "A medical device" in paragraph (3), the words ", not being a Class D medical device,";

(*b*) by inserting, immediately after paragraph (3), the following paragraph:

"(3A) A Class D medical device may qualify for evaluation under an expedited abridged evaluation process, if —

(*a*) at least 2 reference regulatory agencies, each of a foreign jurisdiction, have granted approval for the supply of the medical device in their jurisdictions;