First published in the Government *Gazette*, Electronic Edition, on 30th April 2012 at 5:00 pm.

No. S 169

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS
(MEDICAL DEVICES) (AMENDMENT NO. 2)
REGULATIONS 2012

In exercise of the powers conferred by section 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. 2) Regulations 2012 and shall come into operation on 1st May 2012.

Amendment of regulation 2

2. Regulation 2 of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) (referred to in these Regulations as the principal Regulations) is amended by inserting, immediately after the definition of "specimen receptacle", the following definition:

" "sterile state", in relation to a medical device, means a state free of viable micro-organisms;".

Deletion and substitution of regulation 10A and new regulation 10B

3. Regulation 10A of the principal Regulations is deleted and the following regulations substituted therefor:

"**Exception for clinical trials**

10A. Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product shall not apply to the supply of a

medical device for the purpose of a clinical trial in accordance with the Medicines (Clinical Trials) Regulations (Cap. 176, Rg 3).

Exception for certain Class A medical devices

10B.—(1) Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product shall not apply to the supply of a Class A medical device —

(*a*) that is intended by its product owner to be supplied other than in a sterile state; and

(*b*) that is —

(i) manufactured under a valid manufacturer's licence;

(ii) imported by the supplier under a valid importer's licence; or

(iii) obtained by the supplier from a wholesaler who holds a valid wholesaler's licence.

(2) For the purposes of paragraph (1), a medical device shall be treated as a Class A medical device if it would have been assigned to Class A according to regulation 24 had the medical device been registered.".

Amendment of regulation 11

4. Regulation 11(1) of the principal Regulations is amended by inserting, immediately after the words "medical device" in sub-paragraph (*b*), the words "(but not an unregistered Class A medical device supplied on or after 1st May 2012 in accordance with the requirements specified in regulation 10B)".

New regulation 35A

5. The Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) (referred to in these Regulations as the principal Regulations) are amended by inserting, immediately after regulation 35, the following regulation: