
First published in the *Government Gazette*, Electronic Edition, on 31st August 2012 at 5.00 pm.

No. S 426

**HEALTH PRODUCTS ACT
(CHAPTER 122D)**

**HEALTH PRODUCTS
(MEDICAL DEVICES) (AMENDMENT NO. 4)
REGULATIONS 2012**

In exercise of the powers conferred by sections 71 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. 4) Regulations 2012 and shall come into operation on 1st September 2012.

New regulation 4A

2. 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 4, the following regulation:

“Import of medical devices for personal use

4A. A person may import, without holding an importer’s licence as required under section 13(1) of the Act, any medical device for his personal use or for the personal use of any member of his family, subject to —

- (a) such conditions; and
- (b) such limits on quantity, not exceeding a total quantity of usage of the medical device for 3 months,

as the Authority thinks fit, based on the usage instructions recommended by the manufacturer or product owner of the medical device.”.

Amendment of regulation 11

- 3.** Regulation 11(1) of the principal Regulations is amended —
- (a) by deleting the word “and” at the end of sub-paragraph (e); and
 - (b) by deleting the full-stop at the end of sub-paragraph (f) and substituting a semi-colon, and by inserting immediately thereafter the following sub-paragraphs:
 - “(g) the supply on or after 1st September 2012 of an unregistered Class A or B medical device, not being an unregistered Class A medical device supplied in accordance with the requirements in regulation 10B, which is listed on the Class A or B Medical Device Transition List as published on the Authority’s website; and
 - (h) the supply on or after 1st September 2012 of an unregistered Class C or D medical device which is listed on the Class C or D Medical Device Transition List as published on the Authority’s website.”.

Deletion and substitution of regulations 25 and 26

- 4.** Regulations 25 and 26 of the principal Regulations are deleted and the following regulations substituted therefor:

“Requirement for registration of medical device

25. For the purposes of section 30(2)(a)(iii) of the Act, the prescribed requirements for the registration of a medical device are the safety and performance requirements for the medical device specified in the First Schedule.

Evaluation process

26.—(1) For the purposes of section 33 of the Act, the Authority may, upon an application for the registration of a medical device —

- (a) evaluate the medical device under —
 - (i) an abridged evaluation process; or
 - (ii) an expedited abridged evaluation process; or
- (b) immediately register the medical device.

(2) A medical device may qualify for evaluation under an abridged evaluation process, if —

- (a) any competent regulatory agency of a foreign jurisdiction has granted approval for the supply of the medical device in that jurisdiction;
- (b) the approval by the competent regulatory agency is of a type accepted by the Authority and identified on the Authority's website at the time of the application for the registration of the medical device; and
- (c) the medical device complies with all other conditions specified on the Authority's website.

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

- (a) at least one reference regulatory agency of a foreign jurisdiction has granted approval for the supply of the medical device in that jurisdiction;
- (b) the approval by the reference regulatory agency is of a type accepted by the Authority and identified on the Authority's website at the time of the application for the registration of the medical device; and
- (c) the medical device complies with all other conditions specified on the Authority's website.

(4) The Authority may immediately register a medical device, 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;
- (b) the approval by each of the reference regulatory agencies is of a type accepted by the Authority and identified on the Authority's website at the time of the application for the registration of the medical device; and
- (c) the medical device complies with all other conditions specified on the Authority's website.

(5) A medical device which does not qualify for evaluation under an abridged evaluation process or expedited abridged evaluation process referred to in paragraph (2) or (3) respectively, or for immediate registration under paragraph (4), shall be evaluated under a full evaluation process.