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No. S 646

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;

(*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.";

(*c*) by deleting the words "or (3)" in paragraph (5) and substituting the words "or paragraph (3) or (3A),";

(*d*) by inserting, immediately after paragraph (5), the following paragraph:

"(5A) For the purposes of paragraphs (3) and (3A), a medical device shall be treated as a Class D medical device if it would have been assigned to Class D according to regulation 24 upon the registration of the medical device."; and

(*e*) by inserting, immediately after the words "paragraph (3)" in the definition of "reference regulatory agency" in paragraph (6), the words "or (3A)".

Amendment of Fourth Schedule

3. The Fourth Schedule to the Health Products (Medical Devices) Regulations 2010 is amended —

(*a*) by inserting, immediately after sub-paragraph (ii) of item 2(*c*), the following sub-paragraph:

"	(iii)	by evaluation under an expedited abridged evaluation process referred to in regulation 26(3)	$3,000

"; and

(*b*) by inserting, immediately after sub-paragraph (ii) of item 2(*d*), the following sub-paragraph:

“	(iii)	by evaluation under an expedited abridged evaluation process referred to in regulation 26(3A)	$5,400 ”.

[G.N. Nos. S 542/2011; S 140/2012; S 169/2012; S 370/2012; S 426/2012]

Made this 21st day of December 2012.

JOHN WONG
Chairman,
Health Sciences Authority,
Singapore.

[HSA (HPRG) 401:04/01-000; AG/LLRD/SL/122D/2010/9 Vol. 2]

(To be presented to Parliament under section 72(5) of the Health Products Act).