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No. S 319

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (MEDICAL DEVICES)
(AMENDMENT NO. 2) REGULATIONS 2018

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

Citation and commencement

1. These Regulations are the Health Products (Medical Devices) (Amendment No. 2) Regulations 2018 and come into operation on 1 June 2018.

Amendment of Fourth Schedule

2. The Fourth Schedule to the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) is amended —

(*a*) by deleting the words "50(1) and (2)" in the Schedule reference and substituting "50";

(*b*) by deleting the Schedule heading and substituting the following Part heading:

"PART 1

FEES";

(*c*) by deleting paragraph (*a*) of items 1, 2 and 3;

(*d*) by deleting paragraph (*b*) of item 2 and substituting the following paragraph:

"	(*b*) a Class B medical device —	
	(i) by evaluation under an abridged evaluation process mentioned in regulation 26(2)	$1,800

(ii)	which is immediately registered under regulation 26(4)	$900
(iii)	which is immediately registered under regulation 26(4A)	$900
(iv)	by evaluation under a full evaluation process	$3,500
(v)	by evaluation under a priority full evaluation process mentioned in regulation 26(3C)	$4,100
(vi)	by evaluation under a priority full evaluation process mentioned in regulation 26(3D)	$5,300

";

(*e*) by inserting, immediately after paragraph (*c*) of item 2, the following paragraph:

"

(*ca*)	a Class C medical device that is a standalone mobile application which is immediately registered under regulation 26(4A)	$3,000

";

(*f*) by deleting items 4 and 5 and substituting the following item:

"

4.	Fee for application for the Authority's approval of an application made under regulation 49(2) —	
(*a*)	to make a notification change	Nil
(*b*)	to make an administrative change	$500
(*c*)	to make a change that may affect the safety, quality or efficacy of —	
(i)	a registered Class B medical device	$500
(ii)	a registered Class C medical device	$1,700
(iii)	a registered Class D medical device	$2,800

";

(*g*) by deleting item 7 and substituting the following item:

“

7. Notification fee under regulation 48(2) for changes in particulars in relation to —		
	(*a*) a manufacturer’s licence	$150
	(*b*) an importer’s licence, except an importer’s licence mentioned in item 9	$150
	(*c*) a wholesaler’s licence, except a wholesaler’s licence mentioned in item 9	$150

”;

(*h*) by deleting item 12 and substituting the following item:

“

12. Processing fee in relation to a certificate under regulation 30(1) for a medical device intended for export —		
	(*a*) where the application is for a certificate in respect of one medical device and addressed to one country	$50
	(*b*) for each additional medical device that is mentioned in the certificate	$50

”; and

(*i*) by inserting, immediately after item 12 of Part 1, the following Part:

"PART 2

DEFINITIONS

1. In this Schedule —

"administrative change", for any information submitted to the Authority in relation to the registration of a medical device, means a change to (but not a deletion or removal of) such information that is entered in the Register of Health Products in respect of the medical device, where the change does not affect the safety, quality or efficacy of the medical device;

"notification change" means —

(*a*) a deletion or removal of any information submitted to the Authority in relation to the registration of a medical device that is entered in the Register of Health Products in respect of the medical device, where the deletion or removal does not affect the safety, quality or efficacy of the medical device; or

(*b*) a change to any other information submitted to the Authority in relation to the registration of a medical device, where the change does not affect the safety, quality or efficacy of the medical device.".

[G.N. Nos. S 542/2011; S 140/2012; S 169/2012; S 370/2012; S 426/2012; S 646/2012; S 334/2016; S 538/2016; S 444/2017; S 318/2018]

Made on 17 May 2018.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

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