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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

";