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No. S 1080

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS
(MEDICAL DEVICES)
(AMENDMENT NO. 2) REGULATIONS 2021

In exercise of the powers conferred by section 72(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 2021 and come into operation on 3 January 2022.

Amendment of regulation 2B

2. Regulation 2B(1) of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) (called in these Regulations the principal Regulations) is amended —

(*a*) by deleting the word "either" in sub-paragraph (*b*)(ii) and substituting the word "any";

(*b*) by deleting the words ", medical clinic or clinical laboratory" in sub-paragraph (*b*)(ii)(B) and substituting the words "or medical clinic";

(*c*) by inserting, immediately after sub-paragraph (B) of sub-paragraph (*b*)(ii), the following sub-paragraph:

"(C) a person licensed under the Healthcare Services Act 2020 to provide any licensable healthcare service;";

(*d*) by deleting the word "either" in sub-paragraph (*b*)(iii) and substituting the word "any";

(*e*) by deleting the words ", medical clinic or clinical laboratory" in sub-paragraph (*b*)(iii)(B) and substituting the words "or medical clinic"; and

(*f*) by inserting, immediately after sub-paragraph (B) of sub-paragraph (*b*)(iii), the following sub-paragraph:

"(C) a person licensed under the Healthcare Services Act 2020 to provide any licensable healthcare service;".

Amendment of regulation 3B

3. Regulation 3B of the principal Regulations is amended by deleting paragraph (1) and substituting the following paragraph:

"(1) A person licensed under the Healthcare Services Act 2020 to provide any of the following licensable healthcare services may manufacture a laboratory-developed test without holding a manufacturer's licence under section 12(1) of the Act, if the person manufactures the laboratory-developed test solely for the provision of that licensable healthcare service:

(*a*) a clinical laboratory service;

(*b*) a nuclear medicine assay service;

(*c*) a blood banking service;

(*d*) a cord blood banking service.".

Amendment of regulation 8

4. Regulation 8(1) of the principal Regulations is amended —

(*a*) by deleting the word "or" at the end of sub-paragraph (*a*);

(*b*) by deleting the words ", medical clinic or clinical laboratory" wherever they appear in sub-paragraph (*b*) and substituting in each case the words "or medical clinic"; and

(*c*) by deleting the comma at the end of sub-paragraph (*b*) and substituting a semi-colon, and by inserting immediately thereafter the following sub-paragraph:

"(*c*) a person licensed under the Healthcare Services Act 2020 to provide any licensable healthcare service, for the use of a patient of that person,".

Amendment of Fourth Schedule

5. Part 1 of the Fourth Schedule to the principal Regulations is amended by deleting paragraph (*a*) of item 9 and substituting the following paragraphs:

"(*a*) by a private hospital or medical clinic licensed under the Private Hospitals and Medical Clinics Act 1980, or a person acting on its behalf, where the unregistered medical device is to be used by a patient of the private hospital or medical clinic	$360
(*aa*) by a person licensed under the Healthcare Services Act 2020 to provide any licensable healthcare service, or a person acting on the firstmentioned person's behalf, where the unregistered medical device is to be used by a patient of the firstmentioned person	$360".

[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; S 319/2018; S 90/2019; S 968/2020; S 111/2021]

Made on 30 December 2021.

BENJAMIN ONG
Chairman,
Health Sciences Authority,
Singapore.

[401:04/01-000; AG/LEGIS/SL/122D/2020/5 Vol. 1]

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