First published in the Government *Gazette*, Electronic Edition, on 31st October 2016 at 5:00 pm.

No. S 538

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (MEDICAL DEVICES)
(AMENDMENT NO. 2) REGULATIONS 2016

In exercise of the powers conferred by section 72 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 2016 and come into operation on 1 November 2016.

Amendment of regulation 2

2. Regulation 2 of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) (called in these Regulations the principal Regulations) is amended by inserting, immediately after the definition of "sterile state", the following definition:

" "therapeutic product" means a health product categorised as a therapeutic product in the First Schedule to the Act;".

Amendment of First Schedule

3. The First Schedule to the principal Regulations is amended —

(*a*) by deleting the words "medicinal product" wherever they appear in paragraph 10(2) and substituting in each case the words "therapeutic product or medicinal product";

(*b*) by deleting paragraph 11 and substituting the following paragraph:

"**Verification of incorporated substance**

11. If a medical device incorporates, or is intended to incorporate, as an integral part, a substance that —

(*a*) if used separately, might be considered to be a therapeutic product or medicinal product; and

(*b*) is intended to act on a patient in a way that is ancillary to the medical device,

then —

(i) the safety and quality of the substance must be verified in accordance with the requirements for registering that substance as a therapeutic product under the Act or for issuing a product licence for that substance as a medicinal product under the Medicines Act (Cap. 176), as the case may be; and

(ii) the intended ancillary action of the substance, having regard to the intended purpose of the medical device, must be verified to the Authority's satisfaction by objective evidence.";

(*c*) by inserting, immediately after the words "information about any" in item 24 in the table of paragraph 45(2), the words "therapeutic product or"; and

(*d*) by deleting the words "medicinal product (including any stable derivative of human blood or blood plasma)" in item 25 in the table of paragraph 45(2) and substituting the words "therapeutic product or medicinal product".

Amendment of Third Schedule

4. The Third Schedule to the principal Regulations is amended —

(*a*) by deleting the words "medicinal product" in paragraph 4(3) and substituting the words "therapeutic product";

(*b*) by deleting the words "medicinal product" wherever they appear in paragraphs 11(6)(*a*), 12(4)(*a*), 13(3)(*e*) and 18(1) and (2), and substituting in each case the words "therapeutic product or medicinal product";

(*c*) by inserting, immediately after the word "removing" in the paragraph heading of paragraph 18, the words "therapeutic products or";

(*d*) by deleting paragraph 20 and substituting the following paragraph:

"**Medical devices incorporating therapeutic products or medicinal products**

20. A medical device shall be assigned to Class D if it incorporates, as an integral part, a substance that is liable to act on a human body with an action ancillary to that of the medical device and the substance is —

(*a*) a therapeutic product; or

(*b*) a medicinal product subject to the licensing requirements of section 5 or 6 of the Medicines Act (Cap. 176).";

(*e*) by deleting the words "(e.g. personalised medicinal product)" in paragraph 25(2)(*f*); and

(*f*) by deleting the words "medicinal products" in paragraph 25(2)(*h*) and substituting the words "therapeutic products".

Amendment of Fourth Schedule

5. Item 2 of the Fourth Schedule to the principal Regulations is amended by inserting, immediately after the words "that contains a" in paragraph (*e*), the words "therapeutic product or".

[G.N. Nos. S 542/2011; S 140/2012; S 169/2012; S 370/2012; S 426/2012; S 646/2012; S 334/2016]

Made on 27 October 2016.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

[HSA/LPPD/711:12/58-000; AG/LEGIS/SL/122D/2015/3 Vol. 1]

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