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No. S 111

HEALTH PRODUCTS ACT (CHAPTER 122D)

HEALTH PRODUCTS (MEDICAL DEVICES) (AMENDMENT) 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) Regulations 2021 and come into operation on 1 March 2021.

Amendment of Part II of Third Schedule

2. Part II of the Third Schedule to the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) is amended —

(a) by inserting, immediately after the definition of “active therapeutic medical device” in paragraph 1, the following definition:

““CTGT product” means a health product categorised as a cell, tissue or gene therapy product in the First Schedule to the Act;”;

(b) by inserting, immediately after the words “therapeutic products” in paragraph 2(f), the words “, CTGT products”; and

(c) by deleting sub-paragraph (h) of paragraph 2 and substituting the following sub-paragraph:

“(h) whether the medical device is manufactured from or incorporates any, or any combination of —

- (i) cells or tissues of animal origin; or
 - (ii) derivatives of cells or tissues of animal, human or recombinant origin,
- which are or have been rendered non-viable”.

*[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]*

Made on 15 February 2021.

KANDIAH SATKUNANANTHAM
*Chairman,
Health Sciences Authority,
Singapore.*

[401:04/01-000; AG/LEGIS/SL/122D/2015/3 Vol. 4]

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