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No. S 968

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (MEDICAL DEVICES) (AMENDMENT) REGULATIONS 2020

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) Regulations 2020 and come into operation on 1 December 2020.

New Part IIIA

2. The Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) are amended by inserting, immediately after regulation 13B, the following Part:

"PART IIIA

EXCEPTION — EMERGENCY MEDICAL DEVICES

Manufacture, import and supply of emergency medical devices

13C.—(1) For the purposes of section 12(1) of the Act and without prejudice to regulations 33, 38, 39, 41, 42, 44, 45, 46 and 47, the manufacture of an emergency medical device for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the manufacture of a medical device without a licence.

(2) For the purposes of section 13(1) of the Act and without prejudice to regulations 34, 39, 41, 42, 44, 45, 46 and 47, the import of an emergency medical device for or on behalf of the

Government is a prescribed exception to the prohibition in that provision against the import of a medical device without a licence.

(3) For the purposes of section 14(1) of the Act and without prejudice to regulations 31, 35, 39, 41, 42, 44, 45, 46 and 47, the supply by wholesale of an emergency medical device for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the supply by wholesale of a medical device without a licence.

(4) For the purposes of section 15(1) of the Act and without prejudice to regulations 31, 35, 39, 42, 44, 45, 46 and 47, the supply of an emergency medical device for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the supply of a medical device that is not registered.

(5) In this regulation —

"civil defence emergency" means a civil defence emergency declared under section 102(1) of the Civil Defence Act (Cap. 42);

"emergency medical device" means a medical device that is for such time designated by the Minister as an emergency medical device for the purposes of this regulation, where —

(*a*) the medical device is needed —

(i) to treat or diagnose any medical condition resulting from a civil defence emergency;

(ii) to prevent the spread or possible outbreak of an infectious disease; or

(iii) to treat or diagnose an infectious disease or any medical condition associated with an infectious disease,

where the medical condition or infectious disease is potentially serious or life-threatening; and

(*b*) in the opinion of the Authority, there is —

(i) preliminary scientific evidence that the medical device has the potential —

(A) to treat or diagnose the medical condition resulting from the civil defence emergency;

(B) to prevent the spread or possible outbreak of the infectious disease; or

(C) to treat or diagnose the infectious disease or any medical condition associated with the infectious disease,

as the case may be; and

(ii) ongoing scientific evidence that the potential benefits of the medical device outweigh the known risks of the medical device, to a person on whom the medical device is used;

"infectious disease" has the meaning given by section 2 of the Infectious Diseases Act (Cap. 137).".

[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]

Made on 27 November 2020.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

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