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**No. S 170**

HEALTH PRODUCTS ACT  
(CHAPTER 122D)

HEALTH PRODUCTS  
(MEDICAL DEVICES) (EXEMPTION)  
ORDER 2012

ARRANGEMENT OF PARAGRAPHS

Paragraph

1. Citation and commencement
  2. Definitions
  3. Exemption
  4. Revocation
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In exercise of the powers conferred by section 70 of the Health Products Act, the Health Sciences Authority hereby makes the following Order:

**Citation and commencement**

1. This Order may be cited as the Health Products (Medical Devices) (Exemption) Order 2012 and shall come into operation on 1st May 2012.

**Definitions**

2. In this Order —

“Authority’s website” means the Authority’s Internet website at <http://www.hsa.gov.sg> as may be updated from time to time;

“medical device” means a medical device referred to in the First Schedule to the Act.

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### Exemption

3.—(1) Sections 12(1), (2) and (3), 13(1), (2) and (3) and 14 of the Act shall not apply to any medical device that is manufactured, imported or supplied by wholesale for the purpose of a clinical trial in accordance with the Medicines (Clinical Trials) Regulations (Cap 176, Rg 3).

(2) Sections 12(2) and 13(2) of the Act shall not apply to any unregistered medical device which is supplied in accordance with regulation 10B of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010).

(3) Sections 13(1), (2) and (3) and 14 of the Act shall not apply to the import or supply by wholesale of any medical device —

(a) in respect of which a licence to deal with the medical device is granted under the Radiation Protection Act (Cap. 262); and

(b) which is —

(i) registered under the Act;

(ii) listed on the Class A or B Medical Device Transition List as published on the Authority's website on or before 1st January 2012; or

(iii) listed on the Class C or D Medical Device Transition List as published on the Authority's website on or before 10th August 2010.

### Revocation

4. The Health Products (Medical Devices) (Exemption) Order 2010 (G.N. No. S 437/2010) is revoked.

Made this 30th day of April 2012.

JOHN WONG  
*Chairman,*  
*Health Sciences Authority,*  
*Singapore*

[HSA (HPRG) 401:04/01-000; AG/LLRD/SL/122D/2010/8 Vol. 1]