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## No. S 320

### HEALTH PRODUCTS ACT (CHAPTER 122D)

### HEALTH PRODUCTS ACT (AMENDMENT OF FIRST SCHEDULE) ORDER 2018

In exercise of the powers conferred by section 4(2) of the Health Products Act, the Minister for Health, after consultation with the Health Sciences Authority, makes the following Order:

#### Citation and commencement

1. This Order is the Health Products Act (Amendment of First Schedule) Order 2018 and comes into operation on 1 June 2018.

#### Amendment of First Schedule

2. Item 1 of the First Schedule to the Health Products Act is deleted and the following item substituted therefor:

<i>First column</i>	<i>Second column</i>	<i>Third column</i>
<i>Category</i>	<i>Description</i>	<i>Exceptions and limitations</i>
"1. Medical device	<p>"Medical device" means —</p> <p>(a) any instrument, apparatus, implement, machine, appliance, implant, reagent for <i>in vitro</i> use, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of —</p> <p>(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;</p>	

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- (ii) diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;
  - (iii) investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;
  - (iv) supporting or sustaining life;
  - (v) control of conception;
  - (vi) disinfection of medical devices; or
  - (vii) providing information by means of *in vitro* examination of specimens derived from the human body, for medical or diagnostic purposes,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means; and

- (b) the following articles:
- (i) any implant for the modification or fixation of any body part;
  - (ii) any injectable dermal filler or mucous membrane filler;

- (iii) any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means.”.

Made on 7 May 2018.

CHAN HENG KEE  
*Permanent Secretary,  
Ministry of Health,  
Singapore.*

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