
First published in the Government *Gazette*, Electronic Edition, on 25 May 2018 at 5 pm.

No. S 321

HEALTH PRODUCTS ACT (CHAPTER 122D)

HEALTH PRODUCTS (EXEMPTIONS) (AMENDMENT) ORDER 2018

In exercise of the powers conferred by section 70 of the Health Products Act, the Health Sciences Authority makes the following Order:

Citation and commencement

1. This Order is the Health Products (Exemptions) (Amendment) Order 2018 and comes into operation on 1 June 2018.

Amendment of Second Schedule

2. The Second Schedule to the Health Products (Exemptions) Order 2016 (G.N. No. S 536/2016) is amended by inserting, immediately after paragraph 3, the following paragraphs:

“Adverse effects from use of medical devices not resulting in serious adverse reaction

4.—(1) Section 42(1)(b) of the Act does not apply to a manufacturer, an importer, a supplier or a registrant of a medical device, if the defect in the medical device, or adverse effect that has arisen from the use of the medical device, does not relate to —

- (a) any defect or adverse effect that represents a serious threat to public health;
- (b) an incident that has led to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person; or
- (c) an incident a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person.