**Health Products (Medical Devices) Regulations 2007**

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**No. S 563**

HEALTH PRODUCTS ACT 2007
(ACT 15 OF 2007)

HEALTH PRODUCTS (MEDICAL DEVICES) REGULATIONS 2007

In exercise of the powers conferred by section 72 of the Health Products Act 2007, the Health Sciences Authority, with the approval of the Minister for Health, hereby makes the following Regulations:

## PART I

## PRELIMINARY

### Citation and commencement

**1.** These Regulations may be cited as the Health Products (Medical Devices) Regulations 2007 and shall come into operation on 1st November 2007.

### Definitions

**2.** In these Regulations, unless the context otherwise requires —

"*in vitro* diagnostic product" means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, that is intended by its manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information —

(*a*) concerning a physiological or pathological state;

(*b*) concerning a congenital abnormality;

(*c*) to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients; or

(*d*) to monitor therapeutic measures,

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for *in vitro* diagnostic examination;

"medical device" means a medical device as described in the First Schedule to the Act.

### Application

**3.** These Regulations shall apply to any *in vitro* diagnostic product that is a drug or that contains a drug, as if the product were itself an *in vitro* diagnostic medical device.

## PART II

DUTIES AND OBLIGATIONS OF MANUFACTURERS, IMPORTERS, ETC., OF MEDICAL DEVICES

**Duty to maintain records of supply**

**4.**—(1) Every manufacturer, importer or wholesaler of a medical device shall —

(*a*) keep records of any supply made by him of the medical device; and

(*b*) produce such records for inspection by the Authority or an enforcement officer as and when required by the Authority or enforcement officer.

(2) The records referred to in paragraph (1) shall —

(*a*) contain the following information:

(i) the proprietary name or description of the medical device that was supplied by the manufacturer, importer or wholesaler, as the case may be;

(ii) the date on which the medical device was so supplied;

(iii) the name and address of the person to whom the medical device was so supplied;

(iv) the quantity of the medical device so supplied; and

(v) the identification number or mark (including the control number, lot number, batch number or serial number) of the medical device so supplied; and

(*b*) be retained for the longer of the following periods:

(i) the projected useful life of the medical device; or

(ii) 2 years after the date on which the medical device is so supplied to another person.

(3) Any person who contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) Any person who, in compliance or purported compliance with paragraph (1)(*b*), furnishes the Authority or an enforcement officer with any record which he knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to