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**No. S 950**

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS
(MEDICAL DEVICES) (AMENDMENT NO. 2)
REGULATIONS 2022

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, makes the following Regulations:

## Citation and commencement

**1.** These Regulations are the Health Products (Medical Devices) (Amendment No. 2) Regulations 2022 and come into operation on 9 January 2023.

## Amendment of regulation 2

**2.** In regulation 2 of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) (called in these Regulations the principal Regulations) —

(*a*) after the definition of "laboratory-developed test", insert —

" "licensed healthcare institution" means —

(*a*) any premises or conveyance specified in a licence granted under the Healthcare Services Act 2020 for the provision of any licensable healthcare service; or

(*b*) a private hospital, medical clinic or healthcare establishment that is licensed under the Private Hospitals and Medical Clinics Act 1980;";

(*b*) in the definition of "qualified practitioner", replace paragraph (*b*) with —

"(*b*) a registered dentist;"; and

(*c*) after the definition of "qualified practitioner", insert —

"" "registered dentist" means a person who is registered as a dentist under the Dental Registration Act 1999 whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(*a*) of that Act, when acting in the course of providing dental treatment to a patient under the person's care;".

**Amendment of regulation 3**

**3.** In regulation 3 of the principal Regulations —

(*a*) in paragraph (1), replace "private hospital, medical clinic or healthcare establishment licensed under the Private Hospitals and Medical Clinics Act (Cap. 248) (called in this regulation a healthcare institution)" with "licensed healthcare institution"; and

(*b*) in paragraphs (1)(*a*)(i) and (*b*) and (3), replace "healthcare institution" with "licensed healthcare institution".

**New regulation 3D**

**4.** After regulation 3C of the principal Regulations, insert —

"**Manufacture of specified dental medical devices**

**3D.**—(1) Subject to paragraphs (3) and (4), a person may manufacture a specified dental medical device without holding a manufacturer's licence under section 12(1) of the Act if —

(*a*) the person does not manufacture any medical device that is not a specified dental medical device; and

(*b*) the person has given prior notice of the manufacture of the specified dental medical device to the Authority in accordance with paragraph (2).

(2) The notice mentioned in paragraph (1)(*b*) must —

(*a*) be in the form and manner specified on the Authority's website; and

(*b*) be accompanied by all of the following information in writing:

(i) the particulars of the person giving the notice as required by the Authority;

(ii) the premises where the manufacture is to be carried out;

(iii) a statement of the manufacture involved, including the scope of the manufacturing operations and processes;

(iv) the types of specified dental medical devices manufactured or intended to be manufactured by the person.

(3) To avoid doubt, a person mentioned in paragraph (1) must give notice to the Authority in accordance with paragraph (2) each time the person intends to manufacture a type of specified dental medical device that has not previously been mentioned in the information provided by the person in an earlier notice given under paragraph (1)(*b*).

(4) A person mentioned in paragraph (1) is subject to the duties and obligations of a manufacturer of a medical device under regulations 33(*a*), 38, 39, 41, 42, 44, 45, 46 and 47.

(5) This regulation does not apply to the manufacture of specified dental medical devices in accordance with regulation 3(1) by a person that is a licensed healthcare institution.

(6) In this regulation —

"dental medical device" means any medical device that is intended by its manufacturer to be used on a patient by a registered dentist in the course of providing dental treatment to the patient;

"specified dental medical device" means a dental medical device that —

(*a*) is a custom-made medical device; and

(*b*) would be assigned to Class A or Class B according to regulation 24 if the dental medical device is registered.".

**Amendment of regulation 4**

**5.** In regulation 4(3) of the principal Regulations, replace sub-paragraph (*a*) with —

"(*a*) a licensed healthcare institution; or".

*[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; S 968/2020; S 111/2021; S 1080/2021; S 456/2022]*

Made on 7 December 2022.

BENJAMIN ONG
*Chairperson,*
*Health Sciences Authority,*
*Singapore.*

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(To be presented to Parliament under section 72(5) of the Health Products Act 2007).