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No. S 809

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS
(MEDICAL DEVICES)
(AMENDMENT NO. 2) REGULATIONS 2023

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 2023 and come into operation on 18 December 2023.

Amendment of regulation 2

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

(*a*) replace the definitions of "acute hospital service", "ambulatory surgical centre service", "assisted reproduction service", "blood banking service", "community hospital service", "cord blood banking service", "human tissue banking service", "nuclear medicine service", "outpatient dental service", "outpatient medical service", "outpatient renal dialysis service" and "radiological service" with —

> "'"acute hospital service", "ambulatory surgical centre service", "assisted reproduction service", "blood banking service", "community hospital service", "cord blood banking service", "human tissue banking service", "nuclear medicine service",

"nursing home service", "outpatient dental service", "outpatient medical service", "outpatient renal dialysis service" and "radiological service" have the meanings given by paragraph 2 of the First Schedule to the Healthcare Services Act 2020;";

(*b*) delete the definitions of "nursing home" and "nursing home licensee";

(*c*) replace the definition of "personnel" with —

" "personnel", in relation to a healthcare service licensee providing a licensable healthcare service, means any individual employed or engaged by the healthcare service licensee to assist the licensee in providing the licensable healthcare service;"; and

(*d*) in the definition of "specified healthcare service licensee", after paragraph (*h*), insert —

"(*ha*) nursing home service;".

Amendment of regulation 2B

3. In the principal Regulations, in regulation 2B(1)(*b*) —

(*a*) in sub-paragraph (ii), delete sub-paragraph (B); and

(*b*) in sub-paragraph (iii), delete sub-paragraph (B).

Amendment of regulation 3

4. In the principal Regulations, in regulation 3 —

(*a*) delete paragraph (1); and

(*b*) in paragraph (3), delete sub-paragraph (*a*).

Amendment of regulation 3D

5. In the principal Regulations, in regulation 3D, replace paragraph (5) with —

"(5) This regulation does not apply to the manufacture of specified dental medical devices in accordance with regulation 3(1A) by a specified healthcare service licensee.".

Amendment of regulation 4

6. In the principal Regulations, in regulation 4(3), delete sub-paragraph (*a*).

Amendment of regulation 8

7. In the principal Regulations, in regulation 8(1) —

(*a*) in sub-paragraph (*a*), insert "or" at the end; and

(*b*) delete sub-paragraph (*b*).

[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; S 950/2022; S 434/2023]

Made on 24 November 2023.

BENJAMIN ONG
Chairperson,
Health Sciences Authority,
Singapore.

[78:44/1; 401:04/01-000; AG/LEGIS/SL/122D/2020/5 Vol. 1]

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