(Garuda Emblem)

Ministerial Regulations
Prescribing Fees Pertaining to Medical Devices
B.E. 2563 (2020)

By virtue of Clause 5, paragraph one of the Medical Device Act, B.E. 2551 (2008), the Minister of Public Health issues the following ministerial regulations.

Clause 1 This Ministerial Regulation will apply after thirty days from the date of its publication in the *Government Gazette*.

Clause 2 The Ministerial Regulations Prescribing Fees Pertaining to Medical Devices, B.E. 2552 (2009) shall be repealed.

Clause 3 The following fees shall apply.

(1) Manufacturing establishment registration certificate	per issue	2,000	baht
(2) Import establishment registration certificate	per issue	4,000	baht
(3) Medical device manufacturing license	per issue	10,000	baht
(4) Medical device import license	per issue	20,000	baht
(5) Medical device sale license	per issue	1,000	baht
(6) Medical device advertising license			
(a) advertisement displayed on distributed items (gimmick)	per issue	500	baht
(b) other advertisement	per issue	2,000	baht
(7) Receipt for declaration of specifications regarding manufacturing of medical device	per issue	5,000	baht
(8) Receipt for declaration of specifications regarding import of medical device	per issue	10,000	baht
(9) Medical device manufacturing registration certificate	per issue	1,000	baht
(10) Medical device import registration certificate	per issue	2,000	baht
(11) Certificates			
(a) quality assurance certificate for the manufacture, import, or sale of medical device	per issue	1,000	baht
(b) product determination certificate and formula or composition of medical device	per issue	500	baht
(c) export certificate, manufacturer certificate, and certificate of origin			
1) 1-50 items	per issue	500	baht
2) 51-500 items	per issue	1,000	baht
3) over 500 items	per issue	3,000	baht
(d) label or medical device documentation certificate	per issue	1,000	baht
(e) certificate of medical device manufacture for export	per issue	1,000	baht
(f) other certificates	per issue	500	baht
(12) Medical device assessment certificate pursuant to Clause 22	per issue	1,000	baht

(13) Substitute establishment registration certificate, substitute license, substitute receipt for declaration of specifications, substitute medical device assessment certificate pursuant to Clause 22 and substitute certificate	per issue	500 baht
(14) Establishment registration application	per issue	100 baht
(15) Application for license	per issue	1,000 baht
(16) Application for declaration of specifications	per issue	1,000 baht
(17) Application for registration	per issue	500 baht
(18) Application for relocation or change of place of manufacture, import, sale or storage of medical device	per issue	500 baht
(19) Application for amendment of particulars in an establishment registration certificate	per issue	100 baht
(20) Application for amendment of particulars in a license or other licensed items	per issue	500 baht
(21) Application for amendment of particulars in a receipt for declaration of specifications or other items declared	per issue	500 baht

(22) Renewal of an establishment registration certificate shall be equal to the fee applicable to each issue of the pertinent type of establishment registration certificate.

(23) Renewal of a license shall be equal to the fee applicable to each issue of the pertinent type of license.

(24) Renewal of a receipt for declaration of specifications shall be equal to the fee applicable to each issue of the pertinent type of receipt.

(25) Renewal of the medical device manufacturing registration certificate	per issue	500 baht
(26) Renewal of the medical device import registration certificate	per issue	1,000 baht

Given on 22 December 2020
Anutin Charnvirakul
Minister of Public Health

Remarks: The reason for promulgating these Ministerial Regulations is that the fees pertaining to medical devices should be amended to be in accordance with the fee rates attached to the Medical Device Act B.E. 2551 (2008), as amended by the Medical Device Act B.E. 2562 (2019) taken into conjunction with Clause 5, paragraph one of the Medical Device Act B.E. 2551 (2008) providing for the Minister of Public Health to have the power to issue a ministerial regulation to prescribe fees not exceeding the rates attached to the Act. It is therefore necessary to issue these Ministerial Regulations.