Announcement of the Ministry of Public Health

Subject: Criteria, Methods and Conditions for Organizing to record and report on the manufacture, import or sale of medical devices;

2021

Whereas it is expedient to revise the rules, procedures and conditions for record and report Manufacturing, importing or selling medical devices

By virtue of Section 5 paragraph one and Section 41 (3) of the Act 2008, as amended by the Medical Device Act (No. 2) B.E. 2019, the Minister of Public Health hereby issues the announcement as follows:

verse 1 This announcement shall come into force upon the expiration of the Thirty days from the date of publication in the Government Gazette. onwards

Clause 2 Notification of the Ministry of Public Health Re: Rules, Procedures and Conditions shall be repealed. Keeping records and reports on the manufacture, import or sale of medical devices

Clause 3 The registrant of the establishment of production or water for the importation of medical devices to make a record Manufacturing, importing or selling medical devices that they manufacture or import, keep at the place of production or import. which is specified in the establishment registration certificate for inspection by the competent official for a period of not less than 5 years from the date of manufacture, import or sale, if the medical device produced or imported has an expiration date, year from kept for a period of not less than when it is imported, the expiration date must be at least 5 years from the date of manufacture shall be

(1) in the case of production or water production records import of medical devices

a. Name of medical device

b. date, month, year of manufacture

or import c. license number Detailed notification receipt number Receipt number or number Certificate of manufacturing medical device for export, as the case may be.

E. Expiration date of medical devices (if any)

f. Amount or quantity produced or imported g.

Country of production (in case of import)

H. Name or signature of the operator or supervisor of production or import or an assigned person

(2) in the case of medical device sales records

a. Name of medical device

b. Date, month, year of sale

c. Name of purchaser (individual, juristic person, infirmary or hospital)

D. License number Detailed notification receipt number Receipt number or number
Certificate of manufacturing medical devices for export, as the case may be.

Mon. Number or letter indicating the time of manufacture or serial number (if any)

f. Amount or quantity sold g. Name

or signature of the operator or supervisor of production or importation or assignee

Clause 4. A licensee to manufacture or import a medical device announced by the Minister under section 6 (1) (a) shall prepare an annual report as follows:

(1) a medical device manufacturing licensee shall prepare a medical device production report in the form annexed to
RPD 1 and a report on the sale of medical devices in the form of R.Khor.Por. 1 this notification;

(2), the licensee Medical device importation, medical device importation report form and medical device sales report
RPD 1 form R.Kor.Por. 1 annexed to this notification.

Clause 5 Specifier shall produce or import a medical device announced by the Minister.
Under section 6 (1) (b) prepare an annual report as follows:

(1) medical device manufacturing specifications reporter prepares medical device manufacturing report;
According to the R.Phor.Por. 2 form and the medical device sales report in the form R.Phor.Por. 2 annexed to this announcement

(2) the person giving the details medical device importation, medical device importation report
in the form of Ror.Khor.Por. 2 and the medical device sales report in the form of Ror.Khor.Por. 2 annexed to this announcement

Clause 6 The informer shall produce or import medical devices announced by the Minister under section 6 (1) (c) to prepare an annual report as follows:

(1) Medical device manufacturing informant prepares a medical device production report in accordance with R.Phor.Por. 4 form and a medical device sales report according to R.K.P. 4 - 1 annexed to this notification;

(2) Medical device importer prepares a medical device import report in the form attached to this notification.
R.N.P. 4 and medical device sales report in accordance with R.K.P. 4-1, Article 7, medical

device licensees announced by the Minister under section 6 (3)
Prepare an annual medical device sales report in the form of R.Kor.Por. 3 attached to this announcement.

Clause 8. Medical device manufacturers who have received a certificate of medical device production for export under section 34 shall prepare an annual report on the production of medical devices for export in accordance with the R.P.P. 3 form attached to the announcement. this

Article 9. Reports under Article 4, Article 5, Item 6, Item 7 or Article 8 shall be forwarded to the Licensor in March within the 31 of the following year and collect the A copy of the said form that the officer has already signed.

date for evidence

verse 10 In the event of business termination or renewal, the licensor does not allow the renewal. or revoke the license Detailed notification receipt or cancel the notification receipt to licensee Specifier or informer liquidated not renewing the license Details notification receipt or notification receipt or the licensor does not allow to renew or revoke the license Detailed notification receipt or cancel the notification receipt or the manufacturer Medical devices that have received a certificate of manufacturing medical devices for export under section 34 that have been discontinued, prepare a report under Article 4, Article 5, Article 6, Article 7 or Article 8, as the case may be, and forward it to the licensor. within 90 days from the date of dissolution or not renew or the licensor does not allow renewal or the date of acknowledgment of the revocation order without submitting a report in March of the following year in accordance with along with Article 9. Keep a copy of the aforementioned form which the officer has already received as evidence.

After the report under paragraph one has been prepared, the licensee, specifications provider or informant The report under Article 9 must not be submitted in March of the following year, but a copy of the report under Article 9 that the officer has already received must be kept as evidence.

11 Reports on the manufacture, import or sale of medical devices submitted prior to the date of this notification Regulations shall be deemed to be reports on the manufacture, import or sale of medical devices under this Notification.

Clause 12 The submission of reports on the manufacture, import or sale of medical devices under this Notification shall mainly be done by electronic means. while still unable to proceed by the method electronically The report must be filed at the Food and Drug Administration. Ministry of Health or other places as prescribed by the Secretary-General prescribed by publication in the Government Gazette.

Announced on the 27th day of April B.E. 2556 4

Anutin Charnvirakul

Minister of Health

R.P.P. 1 form

Receipt No. ……

date……

Signed .....Recipient of the report (for officers is the filler)

Medical device production report under section 6 (1) (a).

of the Medical Device Act, B.E. 2551 (2008), and its amendments for the year B.E. ….

Name of licensee …… ……

Name of manufacturing place of medical device …… Establishment registration certificate..... ....

Address: ……..Alley/Soi…… …….road……..……

Village at ……T Sub-district/Kwaeng ……..……A. District/District……..……

Province……..Postal Code…….Number telephone……..

No.	license at	medical device name	Quantity/Quantity produced	production value	note

(signature)..... licensee

(.....)

Form N.P. 1

Receipt No. ……

date……

Signed .....Recipient of the report (for officers is the filler)

Medical device import report under section 6 (1) (a).

of the Medical Device Act B.E. 2551 (2008), B.E. ….

Name of licensee ……

Name of the place of importation of medical devices …… ....

Address: …… Alley/Soi ……Road…… ……Moo……T Sub-district/Kwaeng ……

District/Khet…… Province……Postal Code……

phone number …… ……

No.	license at	medical device name	manufacturer name and Producing country	Imported quantity/quantity	import value	note

(signature)..... licensee

(.....)

Ror.Khor.Por. 1 form

Receipt No. .....
date..... .....
Signed .....Recipient
of the report (for officers is the filler)

Medical device sales report under section 6 (1) (a).

of the Medical Device Act, B.E. 2551 (2008), and its amendments for the year B.E. ....

Name of the licensee..... ....

Place name ( ) manufacture ( ) import .... Certificate of registration of an establishment that.. ....

Address No..... .....Alley/Soi..... ....road..... .....Moo..... .....

Sub-district/Kwaeng..... District District/District..... .... Province.....Postal Code..... .....Telephone number..... .....

No.	License No. (1)	medical device name	manufacturer name and production source	Buyer's name (2)	amount /Quantity sold	value sales	note

note (1) specify the license number of the medical device being sold; (2) specify the name of the purchaser in the case of a medical facility; or the buyer who is the place of sale or sources that are not direct users of the medical device

(signature)..... .licensee
(..... ....)

R.Phor.Por. 2 form

Receipt No. .....

date.....

Signed.....Recipient of the report (for staff to fill out)

Medical device production report under section 6 (1) (b).

of the Medical Device Act, B.E. 2551 (2008), and its amendments for the year B.E. ....

Name of the person who informs the details..... .... Name of manufacturing place of medical device .....Registration certificate of establishment at..... .....

Address: .....Alley/Soi..... .....road.....

Village at .....T Sub-district/Kwaeng .....A. District/District.....

Province.....Postal Code.....Number telephone .....

No.	Receipt detail at	medical device name	Quantity/Quantity produced	production value	note

(signature)..... informant

(.....)

Form N.P. 2

Receipt No.....

date.....

Signed .....Recipient of the report (for staff to fill out)

Medical device import report under section 6 (1) (b).

of the Medical Device Act, B.E. 2551 (2008), and its amendments for the year B.E. ….

Name of the person making the details..... ....

Name of the place of importation of medical devices ……..Registration certificate at …… ……..

Address: ……Alley/Soi…… …….road……

Village at ……T Sub-district/Kwaeng ……..…A. District/District……

Province……..Postal Code…….Number telephone……..

No.	notification detailed list at	medical device name	manufacturer name and Producing country	Imported quantity/quantity	import value	note

(signature)..... informant

(.....)

R.Khor.Por. 2 form

Receipt No.....

date.....

Sign.....Recipient of the report (for staff to fill out)

Medical device sales report under section 6 (1) (b).

of the Medical Device Act B.E. 2551 (2008), B.E. ....

Name of the person making the details..... ....

Name of place ( ) Imported manufacturer ....A certificate of registration of an establishment at ....

Address: ……Alley/Soi…… ……road……

Village at ……T Sub-district/Kwaeng ……A. District/District……

Province……..Postal Code……Number telephone……

No.	Receipt Detail at (1)	medical device name	manufacturer name and production source	Buyer's name (2)	amount /Quantity sold	value sales	note

note

(1) Specify the number of the information receipt of the medical device sold.

(2) Specify the name of the purchaser in the case of a medical facility. or the buyer who is the place of sale or sources that are not direct users of the medical device

(signature)..... .Details informer

(..... ....)

R.Phor.Por. 4 form

Receipt No. .....

date.....

Sign.....Recipient of the report (for staff to fill out)

Medical device production report under section 6 (1) (c).

of the Medical Device Act B.E. 2551 (2008), and its amendments for the year B.E. ....

Name of informant .....

Name of manufacturing place of medical device .....Registration certificate of establishment at..... .....

Address: .....Alley/Soi..... .....road.....

Village at .....T Sub-district/Kwaeng .....A. District/District.....

Province.....Postal Code.....Number telephone .....

No. Information receipt No.	medical device name	Quantity/Quantity produced	production value	note

(signature)..... informer

(.....)

Form N.P. 4

Receipt No. .....

date.....

Sign.....Recipient of the report (for staff to fill out)

Report on the import of medical devices under section 6 (1) (c).

of the Medical Device Act, B.E. 2551 (2008), and its amendments for the year B.E. ....

Name of informant .....

Name of place of importation of medical devices .....Registration certificate of establishment at.....

Address: .....Alley/Soi..... .....road.....

Village at .....T Sub-district/Kwaeng .....A. District/District.....

Province.....Postal Code.....Number telephone.....

No.	notification receipt at	medical device name	manufacturer name and Producing country	Imported quantity/quantity	import value	note

(signature)..... informer

(.....)

R.K.P. Form 4-1

Receipt No. .....

date.....

Signed .....Recipient of the report (for staff to fill out)

Medical device sales report under section 6 (1) (c).

of the Medical Device Act, B.E. 2551 (2008), and its amendments for the year B.E. ....

Name of informant ....

Name of place ( ) Produced ( ) Imported .... Certificate of registration of the establishment that ....

Address: .....Alley/Soi..... .....road.....

Village at .....T Sub-district/Kwaeng .....A. District/District.....

Province.....Postal Code.....Number telephone.....

No.	Information receipt at (1)	medical device name	manufacturer name and production source	Buyer's name (2)	amount /Quantity sold	value sales	note

note

(1) Specify the number of the information receipt of the medical device sold.

(2) Specify the name of the purchaser in the case of a medical facility. or the buyer who is the place of sale or sources that are not direct users of the medical device

(signature)..... .Notifier

(..... ....)

Ror.Khor.Por. 3 form

Receipt No. .....

date.....

Sign.....Recipient of the report (for staff to fill out)

Medical device sales report under section 6 (3)

of the Medical Device Act, B.E. 2551 (2008) and its amendments for the year B.E. ....

Name of the licensee..... .... Name of selling place for medical devices..... ..... Medical device sales license that..... ....

Address: .....Alley/Soi..... .....road.....

Village at .....T Sub-district/Kwaeng .....A. District/District.....

Province.....Postal Code.....Number telephone.....

No.	License No. (1)	medical device name	manufacturer name and production source	Buyer's name (2)	amount /Quantity sold	value sales	note

note

(1) specify the license number of the medical device being sold; (2) specify the name of the purchaser in the case of a medical facility; or the buyer who is the place of sale or sources that are not direct users of the medical device

(Signature).....Licensee

(..... .)

R.Phor.Por. 3 form

Receipt No.....

date.....

Signed .....Recipient of the

report (for staff to fill out)

Report on the production of medical devices for export

as prescribed by the Medical Device Committee under section 34

of the Medical Device Act, B.E. 2008 Annual Year B.E. ....

Name of the recipient of the certificate of manufacture of medical devices for export .....

..... Name of manufacturing place of medical device .....Registration certificate of establishment at..... .....

Address: .....Alley/Soi..... .....road.....

Village at .....T Sub-district/Kwaeng .....A. District/District.....

Province.....Postal Code.....Number telephone .....

No.	certificate of	medical device name	amount/quantity export	Buyer's country	value export	Remaining amount	note

(signature)..... Operator

(.....)