Notification of the Office of the Food and Drug Administration

Re: Specification of Forms under the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices

B.E. 2564 (2021)

Whereas it is appropriate to revise the application forms, receipt for declaration of specifications, and substitute of receipt for declaration of specifications regarding the manufacturing or import of medical devices.

By virtue of clause 12 of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), the secretary-general of the Food and Drug Administration, with the approval of the Medical Device Committee, hereby issue the following notification:

Clause 1 The following shall be repealed:

(1) Notification of the Office of the Food and Drug Administration re: Specification of Forms under the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing of Medical Devices, B.E. 2559 (2016), dated 27 September 2016; and

(2) Notification of the Office of the Food and Drug Administration re: Specification of Forms under the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Import of Medical Devices, B.E. 2559 (2016), dated 27 September 2016.

Clause 2 The declaration of specifications and the issuance of receipt for the declaration of specifications regarding the manufacturing of medical devices shall be in accordance with the attachments to this Notification as follows:

(1) Application for Declaration of Specifications Regarding Manufacturing of Medical Device, under Form Jor.Phor. 1;

(2) Receipt for Declaration of Specifications Regarding Manufacturing of Medical Device, under Form Bor.Jor.Phor. 1;

(3) Application for Renewal of Receipt for Declaration of Specifications Regarding Manufacturing of Medical Device, under Form Jor.Phor. 2;

(4) Application for Substitute of receipt for Declaration of Specifications Regarding Manufacturing of Medical Device, under Form Jor.Phor. 3; and

(5) Application for Amendment of Specifications Regarding Manufacturing of Medical Device, under Form Jor.Phor. 4.

Clause 3 The declaration of specifications and the issuance of receipt for the declaration of specifications regarding the import of medical device shall be in accordance with the attachments to this Notification as follows:

(1) Application for Declaration of Specifications Regarding Import of Medical Device, under Form Jor.Nor. 1;

(2) Receipt for Declaration of Specifications Regarding Import of Medical Device, under Form Bor.Jor.Nor. 1;

(3) Application for Renewal of Receipt for Declaration of Specifications Regarding Import of Medical Device, under Form Jor.Nor. 2;

(4) Application for Substitute of receipt for Declaration of Specifications Regarding Import of Medical Device, under Form Jor.Nor. 3; and

(5) Application for Amendment of Specifications Regarding Import of Medical Device, under Form Jor.Nor. 4.

Clause 4 Any application submitted before this Notification comes into effect, and is still being considered by the licensor, shall be deemed the application under this Notification, *mutatis mutandis*. The licensor may request the applicant to take additional action or submit additional documents or evidence as deemed appropriate.

Clause 5 This Notification takes effect from the date of its publication in the *Government Gazette*.

Issued on 2 February 2021

Paisarn Dunkum

Secretary-general of the Food and Drug Administration

Form Jor.Phor. 1

Receipt No. .....
Date .....
Received by .....
(official to complete)

Application for Declaration of Specifications Regarding Manufacturing of Medical Device

Written at .....

Date .....

I/We .....

Registrant of establishment for manufacturing of medical devices, Registration No. .....

issued on ....., expiring on 31 December .....

facility for manufacturing of medical devices named .....

located at .....

Trok/Soi ..... Road ..... Moo .....

Tambon/Kwaeng ..... Amphoe/Khet .....

Province ..... Postal code ..... Telephone ..... Facsimile .....

with ..... as the person acting on behalf of the juristic person, hereby declare specifications regarding manufacturing of medical devices under section 6(1)(b), together with the following information, document, or evidence:

1. Certification that the person submitting the application is appointed or authorized by the juristic person to carry on the activity, in the case that the applicant is a juristic person;
2. Name of the medical device

   Name in Thai .....

   .....

   Name in English .....

   .....
3. Name and location of product owner / person responsible for marketing the products .....

   .....

   .....
4. Executive summary regarding the medical device
5. Device description
   - 5.1 Scope of medical device .....
   - 5.2 Global Medical Device Nomenclature Code .....
   - 5.3 Device description and features
   - 5.4 Intended use
   - 5.5 Indications

5.6 Instructions for use

5.7 Storage condition

5.8 Shelf life (if applicable)

5.9 Contraindications

5.10 Warnings

5.11 Precautions

5.12 Potential adverse effects

5.13 Alternative therapy

5.14 Details and characteristics of materials used for manufacturing or as part of the medical device

5.15 Other relevant specifications

5.16 Other descriptive information

6. Device labeling and documentation

7. Information about the manufacturing or information about the product owner

8. Documentation showing essential principles of safety and performance of medical device and method used to demonstrate conformity

9. Summary of design verification and validation documents

10. Documentation showing risk analysis

11. Documentation showing how waste generated through the use of these medical devices will be destroyed, compounded, or disposed of after use

12. Certification of quality systems

13. Certification of the intended use, indications, and packaging; the certification of labels; and user manuals issued by the product manufacturer or owner

14. Declaration of conformity issued by the product manufacturer or owner

15. Certification showing the history of the sale of medical devices by the product manufacturer or owner

16. Certification of safety and security offered by the product manufacturer or owner

17. Certification of permission issued by authorities in charge of, and with the power to engage in, the supervision over medical devices in the relevant foreign country; these authorities must be accepted by the Office of the Food and Drug Administration

18. Documentation showing a list of medical devices registered in group registration (if applicable).

Signature.....Applicant

(.....)

Remark: For 4. to 18., provide information by enclosing supporting documents

Form Bor.Jor.Phor. 1

(Garuda Emblem)

Receipt for Declaration of Specifications Regarding Manufacturing of Medical Device

Receipt No. .....

This Receipt is issued to

.....

Registrant of establishment for manufacturing of medical devices, Registration No. ....., to show that it has declared specifications regarding manufacturing of medical devices under section 19 of the Medical Device Act, B.E. 2551 (2008), and its amendment, for the following medical devices .....

.....

.....

Description of the medical device .....

.....

.....

.....

.....

at the facility for manufacturing of medical device named .....

located at No. .....

Trok/Soi ..... Road ..... Moo .....

Tambon/Kwaeng ..... Amphoe/Khet .....

Province ..... Postal code ..... Telephone ..... Facsimile .....

This Receipt is effective until 31 December ..... and is applicable only to the facility specified herein.

Issued on .....

(signature) .....

Position .....

Licensor

Form Jor.Phor. 2

Receipt No. ..... Date ..... Received by..... (official to complete)

Application for Renewal of Receipt for Declaration of Specifications Regarding Manufacturing of Medical Device

Written at.....

Date.....

I/We .....

Declarer of specifications regarding manufacturing of medical devices under Receipt No.....
expiring on 31 December..... and Registrant of establishment for manufacturing of medical devices,
Registration No.....expiring on 31 December .....
at facility for manufacturing of medical devices named.....
located at.....
Trok/Soi.....Road.....Moo.....
Tambon/Kwaeng.....Amphoe/Khet.....
Province.....Postal code.....Telephone.....Facsimile.....
with.....as the person acting on behalf of the juristic person,
hereby apply for the renewal of Receipt for Declaration of Specifications Regarding Manufacturing of Medical Device from 1 January.....

Signature.....Applicant

(.....)

Remark: In the case that the declarer of specification regarding manufacturing of medical device was exempt from providing information or submitting documents or evidence upon application for the declaration, the information or document or evidence shall be submitted in accordance with the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), together with this application.

Form Jor.Phor. 3

Receipt No. .....
Date .....
Received by.....

Application for Substitute of Receipt for Declaration of Specifications Regarding Manufacturing of Medical Device

Written at.....

Date.....

I/We .....

Declarer of specifications regarding manufacturing of medical devices under Receipt No.....

expiring on 31 December..... at facility for manufacturing of medical devices named.....

..... located at.....

Trok/Soi..... Road..... Moo.....

Tambon/Kwaeng..... Amphoe/Khet.....

Province..... Postal code..... Telephone..... Facsimile.....

with..... as the person acting on behalf of the juristic person,

hereby apply for a substitute of the Receipt for Declaration of Specifications Regarding Manufacturing of Medical Device because the original Receipt:

☐ was lost ☐ was destroyed ☐ was damaged;

Together with this application, I/we have enclosed the following evidence:

(1) where the receipt was lost, police report that the Receipt for Declaration of Specifications Regarding Manufacturing of Medical Device was lost, issued by the police station responsible for the location where the receipt was lost; or

(2) where the receipt was destroyed or damaged, the remains of the receipt.

Signature.....Applicant

(.....)

Remark: Insert ✓ in the ☐ in front of the applicable option.

Form Jor.Phor. 4

Receipt No. .....
Date .....
Received by.....

Application for Amendment of Specifications Regarding Manufacturing of Medical Device

Written at.....

Date.....

I/We .....

Declarer of specifications regarding manufacturing of medical devices under Receipt No.....

with.....as the person acting on behalf of the juristic person,

hereby apply for amendment of the specifications regarding manufacturing of medical device as follows:

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.....

Together with this application, I/we have enclosed the documents and evidence in relation to the particulars for which amendment is requested.

Signature.....Applicant

(.....)

No. SorThor

Office of the Food and Drug Administration

Ministry of Public Health

Date.....

Permitted to amend the particulars as requested.

(signature).....

Position.....

Licensor

Form Jor.Nor. 1

Receipt No. ..... Date ..... Received by ..... (official to complete)

Application for Declaration of Specifications Regarding Import of Medical Device

Written at .....

Date .....

I/We .....

Registrant of establishment for import of medical devices, Registration No. .....

issued on ....., expiring on 31 December .....

facility for import of medical devices named .....

located at .....

Trok/Soi ..... Road ..... Moo .....

Tambon/Kwaeng ..... Amphoe/Khet .....

Province ..... Postal code ..... Telephone ..... Facsimile .....

with ..... as the person acting on behalf of the juristic person, hereby declare specifications regarding import of medical devices under section 6(1)(b), together with the following information, document, or evidence:

1. Certification that the person submitting the application is appointed or authorized by the juristic person to carry on the activity, in the case that the applicant is a juristic person;

2. Name of the medical device

   Name in Thai .....

   .....

   Name in English .....

   .....

3. Name and location of medical device manufacturing establishment .....

   .....

   .....

4. Name and location of product owner / person responsible for marketing the products .....

   .....

   .....

5. Executive summary regarding the medical device

6. Device description

   6.1 Scope of medical device .....

   6.2 Global Medical Device Nomenclature Code .....

   6.3 Device description and features

   6.4 Intended use

   6.5 Indications

6.6 Instructions for use

6.7 Storage condition

6.8 Shelf life (if applicable)

6.9 Contraindications

6.10 Warnings

6.11 Precautions

6.12 Potential adverse effects

6.13 Alternative therapy

6.14 Details and characteristics of materials used for manufacturing or as part of the medical device

6.15 Other relevant specifications

6.16 Other descriptive information

7. Device labeling and documentation

8. Information about the manufacturing or information about the product owner

9. Documentation showing essential principles of safety and performance of medical device and method used to demonstrate conformity

10. Summary of design verification and validation documents

11. Documentation showing risk analysis

12. Documentation showing how waste generated through the use of these medical devices will be destroyed, compounded, or disposed of after use

13. Certification of quality systems

14. Certification of the intended use, indications, and packaging; the certification of labels; and user manuals issued by the product manufacturer or owner

15. Declaration of conformity issued by the product manufacturer or owner

16. Certification showing the history of the sale of medical devices by the product manufacturer or owner

17. Certification of safety and security offered by the product manufacturer or owner

18. Certification of permission issued by authorities in charge of, and with the power to engage in, the supervision over medical devices in the relevant foreign country; these authorities must be accepted by the Office of the Food and Drug Administration

19. Power of attorney issued by the product owner appointing the importer in the case of import of medical devices

20. Documentation showing a list of medical devices registered in group registration (if applicable).

Signature.....Applicant

(.....)

Remark: For 5. to 20., provide information by enclosing supporting documents

Form Bor.Jor.Nor. 1

(Garuda Emblem)

Receipt for Declaration of Specifications Regarding Import of Medical Device

Receipt No. .....

This Receipt is issued to

.....

Registrant of establishment for import of medical devices, Registration No. ....., to show that it has declared specifications regarding import of medical devices under section 19 of the Medical Device Act, B.E. 2551 (2008), and its amendment, for the following medical devices .....

.....

.....

Description of the medical device .....

.....

.....

.....

Name and location of the establishment for manufacturing of medical device .....

.....

.....

.....

at the facility for import of medical device named .....

located at No. .....

Trok/Soi ..... Road ..... Moo .....

Tambon/Kwaeng ..... Amphoe/Khet .....

Province ..... Postal code ..... Telephone ..... Facsimile .....

This Receipt is effective until 31 December ..... and is applicable only to the facility specified herein.

Issued on .....

(signature) .....

Position .....

Licensor

Form Jor.Nor. 2

Receipt No. .....
Date .....
Received by.....

Application for Renewal of Receipt for Declaration of Specifications Regarding Import of Medical Device

Written at.....

Date.....

I/We .....

Declarer of specifications regarding import of medical devices under Receipt No. ..... expiring on 31 December ..... and Registrant of establishment for import of medical devices, Registration No. ....., expiring on 31 December ..... facility for import of medical devices named ..... located at .....

Trok/Soi ..... Road ..... Moo .....

Tambon/Kwaeng ..... Amphoe/Khet .....

Province ..... Postal code ..... Telephone ..... Facsimile .....

with ..... as the person acting on behalf of the juristic person, hereby apply for the renewal of Receipt for Declaration of Specifications Regarding Import of Medical Device from 1 January .....

Signature ..... Applicant

(.....)

Remark: In the case that the declarer of specification regarding import of medical advice was exempt from providing information or submitting documents or evidence upon application for the declaration, the information or document or evidence shall be submitted in accordance with the Ministerial Regulations On the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), together with this application.

Form Jor.Nor. 3

Receipt No. .....
Date .....
Received by.....

Application for Substitute of Receipt for Declaration of Specifications Regarding Import of Medical Device

Written at.....

Date.....

I/We .....

Declarer of specification regarding import of medical devices under Receipt No.....

expiring on 31 December.....at facility for import of medical devices named.....

.....located at.....

Trok/Soi.....Road.....Moo.....

Tambon/Kwaeng.....Amphoe/Khet.....

Province.....Postal code.....Telephone.....Facsimile.....

with.....as the person acting on behalf of the juristic person,

hereby apply for a substitute of the Receipt for Declaration of Specifications Regarding Import of Medical Device because the original Receipt:

☐ was lost ☐ was destroyed ☐ was damaged;

Together with this application, I/we have enclosed the following evidence:

(1) where the receipt was lost, police report that the Receipt for Declaration of Specifications Regarding Import of Medical Device was lost, issued by the police station responsible for the location where the receipt was lost; or

(2) where the receipt was destroyed or damaged, the remains of the receipt.

Signature.....Applicant

(.....)

Remark: Insert ✓ in the ☐ in front of the applicable option.

Form Jor.Nor. 4

Receipt No. .....
Date .....
Received by.....

Application for Amendment of Specifications Regarding Import of Medical Device

Written at.....

Date.....

I/We .....

Declarer of specifications regarding import of medical device under Receipt No.....

with.....as the person acting on behalf of the juristic person,

hereby apply for amendment of the specifications regarding import of medical device as follows:

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.....

.....

.....

Together with this application, I/we have enclosed the documents and evidence in relation to the particulars for which amendment is requested.

Signature.....Applicant

(.....)

No. SorThor

Office of the Food and Drug Administration

Ministry of Public Health

Date.....

Permitted to amend the particulars as requested.

(signature).....

Position.....

Licensor