Notification of the Office of the Food and Drug Administration
Re: Specification of Forms under the Ministerial Regulations on the Application for Registration, and the Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2564 (2021)

Whereas it is appropriate to specify the application form and the certificate of registration pursuant to the Ministerial Regulations on the Application for Registration, and Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020).

By virtue of clause 8 of the Ministerial Regulations on the Application for Registration, and Issuance of the Certificate of Registration, of 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 issues the following notification:

Clause 1 The following forms, as attached to this Notification, are required for an application for the registration, and the issuance of the certificate of registration, of the manufacturing or import of medical devices.

(1) Application for the registration of the manufacturing of medical devices, Form Jor.Jor.Phor. 1.

(2) Certificate of the registration of the manufacturing of medical devices, Form Bor.Jor.Jor.Phor. 1.

(3) Application for the registration of the import of medical devices, Form Jor.Jor.Nor. 1.

(4) Certificate of the registration of the import of medical devices, Form Bor.Jor.Jor.Nor. 1.

Clause 2 This Notification takes effect from 17 March 2021.

Issued on 2 February 2021

Paisarn Dunkum

Secretary-general of the Food and Drug Administration

(Translation)

Form Jor.Jor.Phor. 1.

Receipt no. ..... Date of receipt .....

Application for the Registration of the Manufacturing of Medical Devices

I/We (as an individual or juristic person), ...,
registrant of establishment for manufacturing of medical devices, Registration No. .....,
issued on Date: ..... Month: ..... Year: .....,
and expiring on 31 December ....., represented by .....,
who acts on our behalf, hereby apply for the registration of the manufacturing of medical devices under section 6(1)(c). The following particulars, documents, or evidentiary materials are provided to support the application.

1. Product name .....
2. This medical device is for □ humans □ animals
   □ IVD □ non-IVD
3. This application is for the registration of medical device in the form of
   □ a single product; or
   □ grouping of product (please provide information in an attachment; you may add or delete items).

No.	Trade name (English)	Name and location of the manufacturer	Code of the manufacturer	Code of the manufacturer's location	Country of the manufacturer	Name and location of the product owner	Product code	Name attached to the medical device

4. Scope of the medical device .....
5. Global Medical Device Nomenclature (GMDN) .....
6. Device description
7. Product specifications
8. Device label
9. Device documentation (if any)
10. Documentation of overseas registration (if applicable)
11. Report on sterility test (for manufacturing of sterile medical devices)
12. Documentation of testing or calibration testing (for a medical device used for measurement)
13. Declaration of conformity issued by the product manufacturer or owner
14. For a juristic person applicant, certification that the person submitting the registration application is appointed or authorized by the juristic person

(Signature) ....., Applicant
(.....)

Remarks: Please tick / in □ of your choice
An IVD means an in vitro diagnostic medical device.
A non-IVD means a non-in vitro diagnostic medical device.
Animals refers to medical devices that are used with animals only.

(Translation)

Form Bor.Jor.Jor.Phor. 1

(Official Emblem)

Certificate of Registration of the Manufacturing of Medical Devices

Certificate of registration no. .....

This certificate of registration is issued for

.....,

Registrant of establishment for manufacturing of medical devices, Registration No. .....,
to certify that it is the registrant of the manufacturing of medical devices under section 19 of the Medical Device Act, B.E. 2551 (2008), as amended, for the following medical devices .....
.....
.....
Product description .....
.....
.....
The name of the manufacturing facility is .....,
located at ..... Alley (Trok/Soi) ..... Road .....
Moo ..... Subdistrict ..... District .....
Province ..... Postal code ..... Telephone ..... Fax .....
Name and location of the product owner .....
.....

This registration certificate is valid through Date ..... Month .....
Year ....., and is only applicable to the facility indicated in the certificate.

Issued on Date ..... Month ..... Year .....

(Signature) .....
Title .....
Issuer

(Translation)

Form Jor.Jor.Nor. 1.

Receipt no. .....
Date of receipt .....

Application for the Registration of the Import of Medical Devices

I/We (as an individual or juristic person), ...,
registrant of establishment for import of medical devices, Registration No. .....,
issued on Date: ..... Month: ..... Year: .....,
and expiring on 31 December ....., represented by .....,
who acts on our behalf, hereby apply for the registration of the import of medical devices under section 6(1)(c). The following particulars, documents, or evidentiary materials are provided to support the application.

1. Product name .....
2. This medical device is for □ humans □ animals
   □ IVD □ non-IVD
3. This application is for the registration of medical device in the form of
   □ a single product; or
   □ grouping of product (please provide information in an attachment; you may add or delete items).

No.	Trade name (English)	Name and location of the manufacturer	Code of the manufacturer	Code of the manufacturer's location	Country of the manufacturer	Name and location of the product owner	Product code	Name attached to the medical device

4. Scope of the medical device .....
5. Global Medical Device Nomenclature (GMDN) .....
6. Device description
7. Product specifications
8. Device label
9. Device documentation (if any)
10. Documents showing overseas registration (if applicable)
11. Report on sterility test (for import of sterile medical devices)
12. Test report or report on calibration (for a medical device used for measurement)
13. Declaration of conformity issued by the product manufacturer or owner
14. For a juristic person applicant, certification that the person submitting the registration application is appointed or authorized by the juristic person
15. Power of attorney issued by the product owner appointing the applicant as importer

(Signature) ....., Applicant
(.....)

Remarks: Please tick / in □ of your choice
An IVD means an in vitro diagnostic medical device.
A non-IVD means a non-in vitro diagnostic medical device.
Animals refers to medical devices that are used with animals only.

(Translation)

Form Bor.Jor.Jor.Nor. 1

(Official Emblem)

Certificate of Registration of the Import of Medical Devices

Certificate of registration no.

This certificate of registration is issued for

.....,

Registrant of establishment for import of medical devices, Registration No. ....., to certify that it is the registrant of the import of medical devices under section 19 of the Medical Device Act, B.E. 2551 (2008), as amended, for the following medical devices.....
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.....
Product description .....
.....
.....
Name and location of the manufacturing facility .....
.....
.....
The name of the import facility is .....,
located at ..... Alley (Trok/Soi)..... Road .....
Moo ..... Subdistrict ..... District .....
Province ..... Postal code ..... Telephone ..... Fax .....
Name and location of the product owner .....
.....

This registration certificate is valid through Date ..... Month .....
Year ....., and is only applicable to the facility indicated in the certificate.

Issued on Date ..... Month ..... Year .....

(Signature) .....
Title .....
Issuer