

TRANSLATION OF VIETNAMESE MINISTRY OF HEALTH DOCUMENT

Original: QT.HTTB.01

Procedure for Receiving, Evaluating, Issuing, Post-Market Inspection
and Withdrawal of Medical Device Circulation Numbers

Translated by RegDesk DataManager (Rex) using GPT-5.4

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PROCEDURE

Receipt, evaluation, issuance, post-market inspection, and withdrawal of
medical device circulation numbers

QT.HTTB.01

(Issued together with Decision No. s633†/Q■-BYT dated 2 5 /A} /2025 of the Ministry of Health (B■ Y t■))

Prepared by

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Principal Specialist

Department of Infrastructure and
Medical Devices (C■c H■ t■ng và
Thi■t b■ y t■)

Director General

Department of Infrastructure and
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Thi■t b■ y t■)

Standing Deputy Minister

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Code: QT.HTTB.01

EFFECTIVE PROCEDURE

Receipt, evaluation,
appraisal, issuance, post-market inspection,

and withdrawal of circulation numbers
for medical devices | Revision No.: 05

DEPARTMENT OF INFRASTRUCTURE AND MEDICAL DEVICES - MINISTRY OF HEALTH ;

Total number of pages: 60

Relevant persons must study and strictly implement the contents of this regulation.

The contents of this regulation are effective for implementation as a directive of the Ministry of Health leadership.

Each unit shall be distributed only 01 copy (with control stamp affixed). Where units have a need for additional distribution of documents, they must request the ISO secretary for a control-stamped copy. Soft files are provided on the internal network for information sharing.

DISTRIBUTION LIST (specify place of receipt and mark X in the box next to it);

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MONITORING OF REVISION STATUS (revision status compared with the previous version)

Item revised

Page Summary of revised item contents

Replace the phrase "Department of Medical Infrastructure and Devices" with the phrase "Department of Infrastructure and Medical Devices".

Remove the content:

5 Section 2 - "Ministry of Health leadership".

~ "relevant units of the Ministry of Health",

Remove the content:

- Circular No. 19/2021/TT-BYT dated 16 November 2021 of the Minister of Health

providing for document templates and reports for implementation of Decree No. 98/2021/N■-CP;

- Circular No. 10/2023/TT-BYT dated 11 May 2023 of the Minister of Health amending

a number of articles of Circular No. 19/2021/TT-BYT dated 16 November 2021 of the Minister

of Health providing for document templates and reports for implementation of Decree No. 98/2021/N■-CP.

- Circular No. 43/2024/TT-BTC dated 28 June 2024 of the Minister of Finance

providing for collection rates of a number of fees and charges in order to continue removing difficulties and supporting production and business activities.

- Decision No. 3333/Q■-BYT dated 23 August 2023 of the Minister of Health on

authorization to sign a number of documents in the field of medical devices;

- Decision No. 1618/Q■-BYT dated 11 June 2024 of the Minister of Health on

decentralization of signing authority for a number of documents in the field of medical devices;

, ~ Decision No. 1705/Q■-BYT dated 18 June 2024 of the Minister of Health on

announcement of administrative procedures amended and supplemented in the field of medical devices under

the management scope of the Ministry of Health as provided in Decree No. 96/2023/N■-CP dated 30

December 2023 of the Government.

Add the content:

~ Circular No. 64/2025/TT-BTC dated 30 June 2025 of the Minister of Finance providing for collection rates and exemption of a number of fees and charges in order to support enterprises and people;

ì - Circular No. 44/2025/TT-BYT dated 22 November 2025 of the Minister of Health providing

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Name of unit

5 Section 3

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for decentralization of implementation of a number of tasks and settlement of a number of administrative procedures in the field of medical devices under the authority of the Ministry of Health, and providing for document templates, reports for implementation of medical device management,

- Decision No. 3#/Q■-BYT dated 2*! month! year 2025 of the Minister of Health on announcement of administrative procedures amended, supplemented, and abolished in the field of medical devices within the scope of management functions of the Ministry of Health;

- Plan No. 393/KH-BYT dated 02 April 2025 of the Minister of Health on implementation of the Quality Management System according to TCVN ISO 9001:2015 in activities of the Ministry of Health Office in 2025”.

Section 4.1

Replace the phrase “refusal to grant the license” with the phrase “no further consideration”.

Section 4.2

Replace the phrase “CSHT&TBYT” with the phrase “HT&TBYT”.

Replace the phrase “one-stop division” with “receiving officer”.

Replace the phrase “refusal” with the phrase “no further consideration”.

Replace the abbreviation “BPMC” with “CBTN”.

Remove the content:

- “Consolidate and report to the Minister of Health on the results of signing and issuing documents related to issuance of medical device circulation permits on a 6-month and annual basis as prescribed”.

~ “MOH Records Office: Records Office of the Ministry of Health”,

~ “CS: Establishment requesting issuance of circulation numbers for class C, D medical devices”

Add the content

- “TC,CN: Organizations and individuals requesting issuance of circulation numbers for class C, D medical devices”.

Section 5

Replace the phrase “CSHT&TBYT” with the phrase “HT&TBYT”.

Replace the word “CS” with “TC,CN”.

Replace the content "MOH Records Office" with the content "Department Records Office".

Section 5.1

Remove the content:

- "Ministry of Health leadership".

~ "relevant units of the Ministry of Health".

- "Weekly, the Business Registration Division reports to the Department leadership on the list of supplementary dossiers for medical devices for which

the market does not yet have 03 circulation numbers for products with the same medical device name".

- "Supplementary dossiers for medical devices for which the market does not yet have 03 circulation numbers for products with the same medical device name".

Section 5.4

Replace the phrase "refusal to grant the license" with the phrase "no further consideration".

Section 5.5

Replace the phrase "refusal to grant the license" with the phrase "no further consideration".

Section 5.6

Replace the phrase "refusal to grant the license" with the phrase "no further consideration".

24

Section 5.7

Replace the content "Carry out withdrawal of the circulation number on the system and disclose it on the electronic information portal"

with the content "Carry out notification of withdrawal of the circulation number on the system and disclose it on the electronic information portal".

28

Section 5.8

Replace the content "Ministry leadership" with the content "Director General".

31

Section

5.8.2.7

Replace the content "The Director General signs the submission slip to the Ministry leadership for consideration and directive opinions

on the dossier list" with the content "The Director General considers and provides directive opinions on dossiers eligible for priority processing first as prescribed".

31

Section

5.8.2.10 and

Section

5.8.2.11

Merge Section 5.8.2.10 and Section 5.8.2.11 into Section 5.8.2.10; replace the content “The Ministry leadership considers and provides directive opinions” with the content “The Director General considers and provides directive opinions”.

37

Section 5.10

Replace the phrase “refusal to grant” with the phrase “no further consideration”.

Replace the content “Ministry of Health Records Office” with “Department Records Office”.

Revise the content “Ministry of Health (Department of Infrastructure and Medical Devices)” to “Department of Infrastructure and Medical Devices”.

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Replace the content “Fee confirmation time: From Monday to Friday weekly” with the

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38 Product 14 content “Fee confirmation time: From Monday to Friday weekly (except in cases of emergency issuance P8 for epidemic prevention and control, remedying consequences of natural disasters and catastrophes)”.

45 | Section 5.11 _ | Replace the content “Ministry of Health Records Office” with “Department Records Office”.

Replace the content “Form prescribed in Appendix VI issued together with Circular 19/2021/TT-BYT” with the content “Form prescribed in Appendix V issued together with Circular No. 44/2025/TT-BYT”.

Replace the content “Form prescribed in Appendix VII issued together with Circular 19/2021/TT-BYT” with the content “Form prescribed in Appendix VI issued together with Circular No. 44/2025/TT-BYT”.

Replace the content “Form No. 03.01 prescribed in Appendix I issued together with Circular 10/2023/TT-BYT” with the content “Form No. 04 prescribed in Appendix I issued together with Circular No. 44/2025/TT-BYT”.

Section Add the content:

6.1.1.1 ~ “Certificate of medical device clinical trial results issued by the competent authority in cases where clinical trial is required in accordance with law”.

Replace the content “Form No. 03.02 prescribed in Appendix I issued together with Circular 10/2023/TT-BYT” with the content “Form No. 05 prescribed in Appendix I issued together with Circular No. 44/2025/TT-BYT”.

Section 6.1.2.1 Add the content:

- “Certificate of medical device clinical trial results issued by the competent authority in cases where clinical trial is required in accordance with law”.

Replace the content “Form No. 03.03 prescribed in Appendix I issued together with Circular 10/2023/TT-BYT” with the content “Form No. 06 prescribed in Appendix I issued together with Circular No. 44/2025/TT-BYT”.

Replace the content “Form No. 03.04 prescribed in Appendix I issued together with Circular 10/2023/TT-BYT” with the content “Form No. 07 prescribed in Appendix I issued together with Section with Circular No. 44/2025/TT-BYT”.

6.14.1 Add the content:

~ “Certificate of medical device clinical trial results issued by the competent authority in cases where clinical trial is required in accordance with law”.

ÑÏ Replace the content “Form No. 03.05 prescribed in Appendix I issued together with Circular 10/2023/TT-BYT” with the content “Form No. 08 prescribed in Appendix I issued together with Section Circular No. 44/2025/TT-BYT”.

6.1.5.1 Add the content:

- “Certificate of medical device clinical trial results issued by the competent authority in cases where clinical trial is required in accordance with law”.

Replace the content “Ministry of Health” with the content “Department of Infrastructure and Medical Devices”.

Replace the term “CS” with “TC,CN”.

Remove the content:

- “6.4.1. Evaluation for issuance of medical device circulation numbers in accordance with Circular No. 278/2016/TT-BTC dated 14/11/2016 of the Ministry of Finance, specifically:

- Evaluation for initial issuance of circulation numbers for class C, D medical devices: VND 5,000,000/01 dossier.”.

- “6.4.2. Evaluation for issuance of medical device circulation numbers in accordance with Circular No. 64/2020/TT-BTC dated 08/7/2020, Circular No. 112/2020/TT-BTC dated 19/12/2020, Circular No. 47/2021/TT-BTC dated 24/6/2021, Circular No. 120/2021/TT-BTC dated

50 | Section 6.4 _ | 24/12/2021, Circular No. 44/2023/TT-BTC dated 29/6/2023, specifically:

- Evaluation for initial issuance of circulation numbers for class C, D medical devices: VND 3,500,000/01 dossier.”.

- “6.4.3. Circular No. 43/2024/TT-BTC dated 28/6/2024 of the Minister of Finance providing for collection rates of a number of fees and charges in order to continue removing difficulties and supporting production and business activities: Evaluation for initial issuance of class C, D medical devices: VND 4,200,000/01 dossier”.

Add the content:

- Circular No. 64/2025/TT-BTC dated 30 June 2025 of the Minister of Finance

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47 Section 6.I

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Section

S 6.1.3.1

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providing for collection rates and exemption of a number of fees and charges in order to support enterprises and people:

Evaluation for initial issuance of class C, D medical devices: VND 3,000,000/01 dossier".

Replace the content "Ministry of Health leadership" with the content "Leadership of the Department of Infrastructure and Medical Devices".

1. PURPOSE .

This Procedure is developed to provide for uniform implementation of the receipt, evaluation, review of dossiers for issuance or non-issuance, post-market inspection, and withdrawal of circulation

numbers for medical devices in accordance with Decree No. 98/2021/N■-CP dated 08 November 2021 of the Government on management of medical devices (hereinafter referred to as Decree No. 98/2021/N■-CP), Decree No. 07/2023/N■-CP dated 03 March 2023 of the Government amending and supplementing a number of articles of Decree No.

98/2021/N■-CP (hereinafter referred to as Decree No. 07/2023/N■-CP), Decree

No. 96/2023/N■-CP dated 30 December 2023 of the Government detailing

a number of articles of the Law on Medical Examination and Treatment (hereinafter referred to as Decree No. 96/2023/N■-CP), including:

1.1. Review of dossiers requesting initial issuance of circulation numbers for:

- Medical devices with corresponding national technical regulations;
- Medical devices that are measuring instruments requiring type approval in accordance with the law on measurement;
- Medical devices under the fast-track issuance case;
- Medical devices under the emergency issuance case;
- Other medical devices.

1.2. Post-market inspection of dossiers that have been granted circulation numbers for class C, D medical devices under the fast-track issuance and emergency issuance cases.

1.3. Withdrawal of circulation numbers.

2. SCOPE OF APPLICATION

The Department leadership and seconded civil servants and public employees of the Department of Infrastructure and Medical

Devices (C■c H■ t■ng và Thi■t b■ y t■), assigned experts, members of the Advisory Council for issuance of medical device circulation, and organizations and individuals participating in the process of issuance or withdrawal of medical device circulation numbers in accordance with Decree No. 98/2021/N■-CP, Decree No. 07/2023/N■-CP, Decree No. 96/2023/N■-CP. :

3. REFERENCE DOCUMENTS

- Decree No. 98/2021/N■-CP dated 08 November 2021 of the Government on management of medical devices;

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- Decree No. 07/2023/N■-CP dated 03 March 2023 of the Government amending and supplementing a number of articles of Decree No. 98/2021/N■-CP dated 08 November 2021 of the Government on management of medical devices;
- Decree No. 96/2023/N■-CP. dated 30 December 2023 of the Government detailing a number of articles of the Law on Medical Examination and Treatment;
- Circular No. 05/2022/TT-BYT dated 01 August 2022 of the Minister of Health detailing the implementation of a number of articles of Decree No. 98/2021/N■-CP;
- Circular No. 59/2023/TT-BTC dated 30 August 2023 of the Minister of Finance prescribing rates, collection, remittance, management, and use of fees in the healthcare sector,
- Circular No. 64/2025/TT-BTC dated 30 June 2025 of the Minister of Finance prescribing rates and exemptions of a number of fees and charges in order to support enterprises and citizens;
- Circular No. 44/2025/TT-BYT dated 22 November 2025 of the Minister of Health providing for decentralization of implementation of a number of tasks and settlement of a number of administrative procedures in the field of medical devices under the authority of the Ministry of Health and providing forms of documents and reports for implementation of medical device management;
- Decision No. 3Ø/Q■-BYT dated / month 22 year 2025 of the Minister of Health on the announcement of administrative procedures amended, supplemented, or abolished in the field of medical devices under the management functions of the Ministry of Health;
- Decision No. 3322/Q■-BYT dated 06 November 2024 of the Minister of Health on consolidation of the Advisory Council for issuance of medical device circulation numbers;
- Pursuant to Plan No. 393/KH-BYT dated 02 April 2025 of the Minister of Health on implementation of the Quality Management System in accordance with TCVN ISO 9001:2015 in the operations of the Ministry of Health agency in 2025;
- In cases where the documents cited in this procedure are amended, supplemented, or replaced, the newly amended, supplemented, or replaced documents shall be implemented.

4. TERMS AND ABBREVIATIONS

4.1. Terms:

- Circulation number of a medical device means:
 - + Number of declaration of applicable standards for class A, B medical devices;
 - + Number of certificate of registration for circulation for class C, D medical devices.
- A valid dossier requesting first-time issuance of a medical device circulation number is a dossier containing all required dossier components and for which the prescribed fees have been fully paid.

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- Priority dossier means a dossier that is considered and permitted by the Leadership of the Department to be processed in advance in accordance with Clause 21 Article 147 of Decree No. 96/2023/NĐ-CP:

(1). Medical devices manufactured domestically;

(2). Imported medical devices for which an application dossier for import license of medical devices was submitted to the Ministry of Health before 01/01/2022 but for which no import license has yet been granted, and for which an application dossier for a certificate of registration for circulation of medical devices has been submitted;

(3). Chemicals and preparations having the sole purpose of disinfecting medical devices;

(4): Medical devices for implementation of new techniques or new methods applied in medical examination and treatment that have been officially permitted for application by the Ministry of Health in writing but have not yet been granted a circulation number in Vietnam;

(5). Medical devices with no change in information on type/model and product code on the still-valid import license or decision on issuance of registration number for circulation or certificate of registration for circulation already granted, but falling into one of the following cases: l

+ Change of importing establishment or circulation registration entity;

+ Change of name of the manufacturing establishment without change of address of the manufacturing establishment;

+ Change of name of the medical device owner without change of address of the medical device owner; '

(6). Medical devices with no change in information on type/model but with change in product code information because the old product code has ceased production, as stated on one of the following documents: still-valid import license or decision on issuance of registration number for circulation or certificate of registration for circulation already granted;

(7). A previous medical device circulation registration dossier for which the Ministry of Health has issued a written request for supplementation or a written notice of discontinuation of licensing review, where the content of such document relates only to the requirement to update the validity of one of the following documents: letter of authorization of the medical device owner, certificate of conformity with ISO 13485 quality management standards, medical device free sale certificate;

(8). A previous medical device circulation registration dossier for which the Ministry of Health has issued a written request for supplementation or a written notice of discontinuation of licensing review, where the content of such document only requires amendment or supplementation of the name of the medical device.

- Review Team: Established by the Department of Infrastructure and Medical Devices and organized to review dossiers before submission to the Advisory Council for issuance of medical device circulation numbers.

- Classification Team: Established by the Ministry of Health and operating in accordance with the working regulations of the Classification Team. :

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4.2. Abbreviations:

- TBYT: Medical device.

- C^{HT&TBYT}: C^H t^{ng} và Thi^t b^y t ^{(Department of Infrastructure and Medical Devices) - B^Y t ^{(Ministry of Health).}}

- SLH: Medical device circulation number.

-TC,CN: Organizations and individuals requesting issuance of circulation numbers for class C, D medical devices

- HS: Dossier requesting first-time issuance of circulation numbers for class C, D medical devices.

- CBTN: Receiving officer of C■c HT&TBYT is a civil servant or seconded public employee at C■c HT&TBYT assigned by the Leadership of C■c HT&TBYT to perform such duties.
- BPKT: Accounting Division of C■c HT&TBYT.
- VT C■c: Records and archives office of C■c HT&TBYT.
- C■c tr■ng: Director General of C■c HT&TBYT.
- Phó C■c tr■ng: Deputy Director General of C■c HT&TBYT.
- P.■KKD: Medical Device Registration and Trading Management Division.
- H■ th■ng: Software system for provision of online public services for medical device management.
- CV T■: Appraisal specialist is a civil servant or seconded public employee at C■c HT&TBYT assigned by the Leadership of C■c HT&TBYT to monitor, appraise, and compile appraisal results of dossiers requesting first-time issuance of medical device circulation numbers.
- CV TD: Monitoring specialist is a civil servant or seconded public employee at C■c HT&TBYT assigned by the Leadership of C■c HT&TBYT to monitor and compile post-market inspection results of dossiers that have been granted medical device circulation numbers.
- CV TH: General specialist is a civil servant or seconded public employee at C■c HT&TBYT assigned by the Leadership of C■c HT&TBYT to perform one or several of the following contents: (1). Compile and submit to the Leadership of C■c HT&TBYT the list of dossiers requesting first-time issuance of medical device circulation numbers to be prioritized for advance processing; (2). Compile the list of dossiers before Review Team meetings; (3). Compile the list of dossiers before submission to the Council; (4). Seek opinions of the Classification Team for dossiers on which the Review Team or the Council has opinions regarding classification results; (5). Seek opinions of relevant Departments/Bureaus and units as requested by the Council; (6). Submit to the Leadership of C■c HT&TBYT the list for issuance of circulation numbers and the list for discontinuation of review for issuance of circulation numbers; (7). Report post-market inspection results of dossiers.
- H■: Advisory Council for issuance of medical device circulation numbers established by the Ministry of Health.
- ■■n v■ th■m ■■nh: Unit designated and contracted by the Ministry of Health to appraise and conduct post-market inspection of the technical dossier and clinical dossier within the dossier.

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5. PROCEDURAL CONTENT

5.1. General provisions:

5.1.1. The procedure for receipt, appraisal, issuance, post-market inspection, and withdrawal of medical device circulation numbers shall be uniformly applied and implemented by the Leadership of C■c HT&TBYT, civil servants and seconded public employees at C■c HT&TBYT, experts, dossier appraisal units for applications requesting first-time issuance of medical device circulation numbers, and the Advisory Council for issuance of medical device circulation numbers. In cases where corresponding contents prescribed in other referenced procedures differ from the contents prescribed in this procedure, implementation shall uniformly follow the provisions of this procedure.

5.1.2. This procedure applies to processing of cases submitting dossiers in accordance with Article 30 of Decree No. 98/2021/N■-CP.

5.1.3. Dossiers shall be considered and processed according to the following principles:

- Priority dossiers shall be processed before non-priority dossiers.
- Earlier submitted dossiers shall be processed first.

5.1.3.1. Dossiers under Clauses 3 and 4 Article 30 of Decree No. 98/2021/N[■]-CP (fast-track issuance cases; emergency issuance cases):

The System assigns dossiers in the following order:

- (a). Priority dossiers under emergency issuance cases.
- (b). Non-priority dossiers under emergency issuance cases.
- (e). Priority dossiers under fast-track issuance cases.
- (d). Non-priority dossiers under fast-track issuance cases.

(■). For dossiers from items (a) to (d), the System randomly assigns them to appraisal specialists; supplemented dossiers shall be reassigned to the appraisal specialist who conducted the first appraisal.

5.1.3.2. Dossiers under Clause 1, Clause 2 and Clause 5 Article 30 of Decree No. 98/2021/N[■]-CP (medical devices having corresponding national technical regulations; medical devices that are measuring instruments requiring type approval under the law on measurement; other class C, D medical devices): i

(1) The System assigns dossiers for appraisal specialists and appraisal units to process in the following order:

- (a). Priority dossiers (including supplemented dossiers);
- (b). Non-priority dossiers.

(2) Assignment of dossiers to appraisal specialists shall be random, and the total number of dossiers of appraisal specialists under processing shall not differ by more than 01 dossier.

5.1.4. Post-market inspection of dossiers that have been granted circulation numbers shall be carried out as follows: Implemented according to the plan.

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5.2. Provisions on submission of supplemented dossiers

5.2.1. The supplementation period is within 90 days from the date C[■]c HT&TBYT issues an official letter notifying the establishment to supplement the dossier.

5.2.2. Number of supplementations:

- No limit on the number of dossier supplementations for medical devices under emergency issuance cases.
- 03 times/dossier for other class C, D medical devices submitted before 01/01/2024! or medical devices under fast-track issuance cases.
- 05 times/dossier for other class C, D medical devices submitted from 01/01/2024? or medical devices having corresponding national technical regulations or medical devices that are measuring instruments requiring type approval under the law on measurement.

5.2.3. After 90 days from the date C[■]c HT&TBYT issues the notification request, if the establishment does not supplement or amend the dossier, or if the permitted number of supplementations prescribed in Section 5.2.2 above has been exhausted and the dossier still does not meet requirements, the procedure for requesting issuance of a circulation number must be restarted from the beginning.

5.3. For dossiers for which there remain differing opinions within the Review Team, C[■]c HT&TBYT shall consider submission to seek the opinion of the H[■].

5.4. Flowchart of dossier appraisal under Clause 1 and Clause 2 Article 30 of Decree No. 98/2021/N■-CP: (i) having corresponding national technical regulations and

(ii) being measuring instruments requiring type approval under the law on measurement

Step | Time for

Implementation implementation Sequence of implementation to be implemented

I. Dossier submission and fee confirmation

TC,CN 5.4.1 | Daily

| Dossier components Monday -->

| incomplete ■ &

Review and Tuesday 6 every

CBTN ? 5.4.2 | week

receipt of dossier

Dossier components

complete

1 Implemented in accordance with Clause 18 Article 1 of Decree No. 07/2023/N■-CP.

? Implemented in accordance with Clause 5 Article 32 of Decree No. 98/2021/N■-CP

3 Implemented in accordance with Clause 2 Article 32 of Decree No. 98/2021/N■-CP.

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Daily

| Consolidate and draft the document requesting supplementation of the dossier

TC,CN

Monday —>

payment of fees ... Friday

...

Transfer to step 5.4.5

II. Receipt, appraisal, and notification of the results of the first-time appraisal of the dossier

System

CVT■

assign dossier 5.4.5 | 01 day

Appraising

unit

—| —i

- Legal dossier

Appraising j_m.== '—— time 8

unit, CV : Appraisal period

T■ I Appraise dossier Technical dossier appraisal

5.4.6

Dossier: 08

days.

— Clinical dossier

Appraisal satisfactory

or requiring solicitation of

Handling appraisal opinions on content

results of dossier 01 day.

dossier appraisal

CVT■ 5.4.7

Appraisal

Draft notification. Transfer to

step 5.4.15

=~+ ↗

CVT■ 5.4.8 | 1/2 day,

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T■RKT Approve draft Official Letter 5.4.9 | 1/2 day

" Director of Review, sign approval of Official Letter 5.4.10. | 1/2 day

the Department

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VTL■M Issue Official Letter 5.4.11 | 01 day

III. Appraisal and notification of appraisal results of supplementary dossier

TC,CN Submit supplementary dossier 5.4.12 | Daily

Legal dossier

, TEEN ST Appraisal time

System, HÁT m—=>—> nU BI

Appraising Product dossier + Technical dossier 5.4.13 ...

unit, CV Š ↗ c="

„ Appraising unit ... code

Clinical dossier

Handling appraisal results:

supplementary dossier

Supplementary dossier

satisfactory

supplementary dossier or supplementary dossier

CVT■ unsatisfactory, or 5th supplementation:

5.4.14 | 01 day

or requiring

solicitation of opinions

Transfer to Transfer to | on content

step 5.4.8 step 5.4.15

IV. Review Team meeting

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13

Consolidate the list for Review Team meeting

After

receiving opinions

from the

Classification Team

Review meeting, reach consensus

L

Review the dossier list to be submitted to the Council

CVTH 5.4.15 02 days

Request for

reconsideration

CVTH seeks Specialist

opinions from the Classification Team

before

Leadership

nà - Review and approve dossiers

for submission to the Council 01 day

Request for Agree 34.16 _

reconsideration for submission to the Council

Transfer to step 5.4.7 Sign document to send to the Council

V. Submission to the Council

E—=

Consolidate the dossier list submitted by the Department of Infrastructure and Medical Devices (C■c HT&TBYT)

Council Secretary reports to the Council Chairperson 5.4.17

T= 1/2 day

■i 05 à

"ý Agree on meeting schedule and „__ days

Council Chairperson dossier list for Council meeting 5.4.18 | before the

Council meeting

*

During the
Council members Council meeting to review and adopt | 5.4.19 | Council
meeting
01 day

Finalize the meeting minutes, consolidate:
Council Secretary dossier list approved by the Council, 5.4.20 | 02 days
requests for supplementation and cases not continued for review:

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14

Chairperson Review and approve the contents of the meeting minutes, dossier list
of the Council, approved by the Council, requests for supplementation and 5.4.21 | 01 day
Council members cases not continued for review

I - _—

Head Sign document transferring to the Department of Infrastructure and Medical Devices (C■c HT&TBYT)
of the Secretariat Minutes and Conclusions of the Council 5.4.22 | 1/2 day
Council Secretariat Team

VI. Finalization of procedures for issuance of circulation number
01 day

Deputy Director Review the Council's conclusions 5.4.23
of the Department

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Dossiers with medical devices granted Dossiers with requirements of the
circulation number, dossiers with medical devices Council requiring supplementation/
not granted circulation number explanation

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CV T■ and dossiers requiring solicitation of opinions from |
CVTH related Departments/Bureaus and units Transfer 5.4.24
to step
5.4.7

■ L——— -

- Transfer dossier to CV T■ ———— 02 days
- CV TH reports to Department Leadership and transfers
for seeking opinions from Departments/Bureaus ——\ to step
and related units 34.15 +

Leadership Review and approve draft Decisions, :
P.■KKD on issuance of circulation numbers 5.4.25 | 1/2 day
and document on not continuing review

15

Review,

approve

Deputy Director 5.4/26 | 01 day

of the Department

Agree Return to

step 5.4.24

Review,

Director sign approval

5.4.27 | 01 day

Return to

step 5.4.24

Department Registry Issue, return results 5.4.28 | 01 day

Circulation number

—|

5.5. Flowchart of receipt, processing, appraisal, and approval of dossiers as prescribed in Clause 3 and Clause 4, Article 30 of Decree No. 98/2021/N■-CP: (ii) cases eligible for expedited issuance, (iv) cases eligible for emergency issuance

Step | Time for

Implementation Sequence of implementation implementation

1. Submission of dossier and fee confirmation

TC,CN 5.5.1 | Daily

—|

Monday —>

Review, receive Friday weekly

CBTN:

receive dossier 5.5.2 | week

Dossier components

complete d

16

TC, CN 5.5.3. | Daily

Confirm Monday —>

fee payment Friday every

BPKT Insufficient fee week

5.5.4

Transfer to step 5.5.5

II. Receipt, evaluation, and notification of the dossier evaluation result for the first submission

System Receipt, 555 1/2 day

assign dossier to appraisal officer (CVT■) “

—t—

Evaluation not satisfactory

Dossier

evaluation

CVT■ Evaluate 5.5.6 01 day

satisfactory or

need to seek opinions on

content Transfer to

step 5.5.13

01 day

CVT■ Compile, draft document requesting dossier supplementation 5.5.7

Leadership h

1 H■: 1/2

P.■KKD Approve draft Official Letter _ | By day

Deputy Director]

Approve and sign Official Letter I 5.5.9. |1/2 day

C■c Secretariat Issue Official Letter 5.5.10 | 01 day I

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17

III. Evaluation and notification of the evaluation result of supplemented dossier

Submit supplemented dossier

TC, CN 5.5.11 | Daily

Evaluate

supplemented dossier

Supplemented

dossier

System, not

CVT■ x

Supplemented dossier satisfactory

or 3rd supplemented dossier

not satisfactory

or need to seek
opinions on content

5.5.12 | 01 day

Transfer to
step 5.5.7

Transfer to
step 5.5.13

IV. Review Team meeting

NEESE=

■i

Compile agenda/list of dossiers for Review Team meeting

After
obtaining
opinions
of the
Classification
Team

Review meeting, unify

5.5.13

the list of dossiers to be submitted to the Council

Review Team,
CVTH

Seek opinions on
classification
results

Unify submission || Transfer
to leadership of the to
Classification Team C■c (Department) for review step
before submission to 5.5.6
the Council

— Page 18 —

18

Review and approve dossiers
for submission to the Council

Leadership of

C■c HT&TBYT (Department of Infrastructure and Medical Devices) Request re- 5.5.14 | 1/2 day

consideration

Transfer to

step 5.5.6 I

V. Submit to the Council

: Compile the list of dossiers submitted by C■c HT&TBYT

Council Secretariat Submit to the Council, report to the Chairperson of the Council | 3-32 | 01 day

xui Unify meeting schedule and list of dossiers 01 day

Chairperson of the Council for Council meeting 5.5.16 before the

+ Council meeting

3 tà Council meeting to review and approve During the

KG 5.5.17 |Council

meeting

1/2 day

Finalize meeting minutes, compile 01 day

the list of dossiers approved by the Council, dossiers after the end

Council Secretary requiring supplementation and dossiers not to continue being considered 320516 of the

] meeting

Chairperson Review and approve the contents of the minutes, the list of dossiers

of the Council, approved by the Council, requiring supplementation and not continuing | | 5.5.19 | 1/2 day

Council members to be considered

Head of the mm. R

Council Secretariat Team Sign document transferring to C■c HT&TBYT 5.5.20. | 1/2 day

the Minutes and Conclusion of the Council

VI. Finalization of procedures for issuance of circulation number

Deputy Director

Review Conclusion

■ 5521 1/2 day

of the Council

“HI■P

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19

Dossiers with medical devices granted Dossiers with Council

circulation numbers (SLH), dossiers with medical devices requirements requiring supplementation/

not granted circulation numbers explanation

C■c Secretariat

Approve

Disagree

Transfer back

step 5.5.22

Issue, return results

circulation number

Dossiers requiring opinions from Transfer

6 appraisal officer and relevant V/C (Department/Bureau), units to

step 5.5.6 5.5.22 | 1/2 day

CV T and

CVTH

- Transfer dossier to appraisal officer (CVT) Transfer

- CVTH reports to C leadership to seek to step

opinions from relevant V/C, units 5.5.13

—

Leadership Review, approve draft Decisions, circulation numbers, and 1.

P.KKD documents on not continuing consideration 3.3.23. | 1/2 day

—E—

Deputy Director „ F R

Review, approve

Disagree 5.5.24 | 1/2 day

Agree Transfer back

—T to step 5.5.22

Review, sign approval

Director

5.5.26

5.5.25 | 1/2 day

1/4 day

...

5.6. Flowchart of the procedure for evaluation of other dossiers as prescribed in Clause 5 Article 30

Decree No. 98/2021/N-CP.

Step | Time for

Implementation Sequence of implementation implementation

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2@).

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20

I. Submission of dossier and fee confirmation

TC, CN 5.6.1 | Daily

Monday →

→. Friday every

Review, receive g
Receiving Officer & À
dossier 5.6.2 | week
Dossier
components complete
TC, CN 5.6.3 | Daily
Confirm Monday —
fee payment Tu Friday every
Fee not yet sufficient À
BPKT Fee sufficient I 5.6.4 week,
Transfer to step 5.6.5
II. Receipt, evaluation, and notification of the evaluation result of the first-submitted dossier
Assign dossier
F Dossiers submitted from Dossiers submitted before
System date date
01/01/2024 01/01/2024 5.6.5 | 1/2 day
Appraising
unit
Em]
: Legal dossier
Appraising Time for
unit, Evaluate dossier | Technical dossier evaluation
CVT■ | Technical dossier | | 5.6.6 dossier: 15
| days.
Appraising Clinical dossier
unit Rí —
@s}-

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21

Assessment did not pass

Processing the
assessment results
of the dossier

Assessment of the
CVTP■ passed or
requires seeking opinions on
the content

Proceed to
step 5.6.16

5.6.7 01 day

CVT consolidates and drafts the document requesting supplementation of the dossier

5.6.8 |02 days

+ = _

Leadership approves the draft Official Letter

P. KKD | E 5.6.9. |01 day

Deputy Director | Signs approval of the Official Letter

General 5.6.10 | 01 day

Office of the Department

Issue the Official Letter

5.6.11 |01 day

II. Assessment and notification of assessment results of the supplemented dossier

L

01/01/2024 dated 01/01/2024

Appraising unit]

TC, CN From dossier submission date 5.6.12. | Daily

FE _

Assign dossiers

Supplemented dossiers of dossiers submitted from date Supplemented dossiers of
dossiers previously submitted

5.6.13 | 1/2 day

|

Unit | Clinical dossier |

assessment S Clinical

I

CV T — R

>|_ Legal dossier

- Assess dossier Time

System, supplemented dossier Technical dossier | | s ç i, | assessment

Appraising unit TS dossier: 15 1

days.

of the dossier Supplemented dossier passed
or final supplemented
dossier

CVT ■ final did not pass |5.6.15 | 01 day

or requires seeking

opinions on the

content

Proceed to, Proceed to

step 5.6.8 step 5.6.16

IV. Review Team meeting

| Consolidate the list for Review Team meeting |

After receiving

opinions of the

classification team

Review meeting, unify

Review Team, HN BHSSEEP HHHH. H ■ 5616 |daily

CVTH

CV TH seeks

opinions from the classification

team for review

before submission to the Council

1H RE |

Review dossiers

for submission to the Council

Department

Leadership 5.6.17 |02 days

of HT&TBYT

V. Submit to the Council

ri B ■

Council Secretary Consolidate the list of dossiers submitted by the Department of HT&TBYT 5.6.18 | 01 day

to the Council, report to the Chairman of the Council

+ +—

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2

Council

Minutes and Conclusion of the Council

V. Complete procedures for issuance of circulation number

P : 05 days

Chairman of the Council Agree on the meeting schedule and dossier list 5.619 |before the Council meeting date

‡ During the

Members of the Hold Council meeting to review and approve during the Council

5.620 |)

Council meeting

meeting 01 day

Complete the meeting minutes, consolidate

Council Secretary the list of dossiers approved by the Council, 56.21 | 03 days

requests for supplementation and dossiers not to be further considered

Chairman Reviews and approves the contents of the meeting minutes, the list of dossiers

of the Council, dossiers approved by the Council, requests for supplementation and dossiers not || 5.622 | 02 days

Council members to be further considered

| Head of : : H 01 day

Secretariat Team Sign documents submitted to the Department of HT&TBYT 5.6.23 ■

relevant

- Transfer the dossier back to CV

T■

- CV TH reports to Department

Leadership to seek opinions of

02 days

Consider the

Deputy Director Conclusion of the Council

General 5.6.24

■

CVTH, R If dossiers need to

CVT■ dossier with medical devices update circulation number, dossiers with requirements of

dossiers with medical devices not granted the Council must be supplemented/

circulation number explained

Dossiers requiring opinions Proceed to

from other Departments/Bureaus, units step 5.6.7 5.6.25 | 03 days

E275

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24

Circulation number

Leadership ■

of P.■KKD Review and approve draft Decisions, 5.6.26 | 01 day

| circulation numbers and documents on non-continuation of consideration

Review,

approve

Deputy D

■ng 5.6.27 | 01 day

Return to

step 5.6.25

Review,

sign approval

Director General : 5.6.28 | 01 day

step 5.6.25

Office of the Department Issue and return results 5.6/29 |01 day

5.7. Flowchart of the process for assessment and post-market inspection of dossiers already granted circulation numbers according to plan

for class C and D medical devices under the provisions of Clause 3, Clause 4, Article 32 of Decree

No. 98/2021/N■-CP: (i) subject to expedited issuance, (ii) subject to emergency issuance

Implementation Sequence of implementation actually carried out

implementation | (working

days) _

1. Assign dossiers, assess dossiers

T_ £

z . ` According to the

System dossiers already granted circulation numbers 5.7.1 | approved

|} plan

—

\ #}k-

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25

8 CVT■

System

implements according to 02 days

the list Assign dossiers 572 | "8y

of the

Department

CVT■ reviews

Legal dossier

x Time

Appraising unit Assess, post-market — assessment time

assessment, | | inspection, review dossier Technical dossier | | s;+ Íns;3■

CVT■ days.

Appraising unit Clinical dossier

assessment =————

—

CVT■ | Process assessment and post-market inspection results | 5.74. |02 days

— SIEE

({___ —__ ■

Post-market inspection dossier passed Post-market inspection dossier did not

CVTH requirements meet requirements 5.7.5 |02 days

Proceed to step 5.7.16

— —]

CVT■, - I R -

CVTH, Work with the establishment regarding the post-market inspection dossier to clarify the

Department contents and consider whether requirements are met or not met 3.7.6 10 days

Leadership m1

II. Submit to the Council.

—

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26

— —====

Compile the dossier list for submission to the Council

After obtaining

the opinions of the

Classification Team

The leadership of the Department of

Infrastructure and Medical Devices (C■c HT&TBYT) chairs a meeting

to review and reach consensus

The dossier-list review team for submission to the Council 3z; |04 days

CVTH Request for opinions Proposal

on the re-classification review result

CVTH requests The Classification Team Submit to the Leadership Move to

opinions of the unanimous of the Department next step

Classification Team for review

before

submission to

the Council

Post-market

inspection dossier list

nh m■p 5.78 :

Department Proposal 02 days

for re-review

Specialist sends written request to the Council

Move to step 5.7.4 iy■n T si

„ Compile the dossier list by the Department of Infrastructure and Medical Devices (

Secretary of the Council | submitted to the Council, report to the Chairman of the Council 3.72 |01 day

F: † —?-

Official Unify meeting schedule and 57:10 05 days before

Chairman of the Council | dossier list " Council meeting date

à ?a Council meeting to review and approve | During the

Members 57.11 |Council

se ■ meeting

— 01 day

h ■ 03 days

Finalize the meeting minutes, compile

the list of circulation numbers proposed by the Council for withdrawal: 57.12

ý BH X KD proposed circulation number withdrawal

_‡

8.4

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27

x Review and approve the contents of the meeting minutes, : b

Chairman of the Council | list of circulation numbers proposed by the Council for withdrawal 3.713 |02 days

Department Minutes and Conclusions of the Council 5.7.14 |01 day

HT&TBYT

II. Complete procedures for continuation or withdrawal of circulation numbers

Deputy Director 5 01 day

| Review the Conclusions of the Council 5.7.15 Zg

|

CVTH Draft submission report on post-market inspection results 5.7.16 | 03 days

and draft Decision on withdrawal of circulation numbers

|-

Leadership + T

Registration Division (P.■KKD) | Review and approve the drafts 5.7.17 |01 day

T ■

Review and approve

Director 5.7.18 | 01 day

Return to

step 5.7.16

Review, approve post-market

inspection results and sign approval of

€ 3 the Decision on withdrawal of circulation numbers .

Department Director 5.7.19 | 02 days

Return to

step 5.7.16

Department Records Office | Issue the Decision on withdrawal of circulation numbers | 5.7.20 | 01 day,

Implement notification of circulation number withdrawal

CVTD on the system and publicize on 3.7.21 | 01 day

the electronic information portal

Mi

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28

5.8. Regulations on review of priority dossiers

5.8.1. General provisions

After receiving a written request together with supporting documents from the organization/individual (TC,CN) requesting priority processing of a dossier, the leadership of the Department of Infrastructure and Medical Devices (C■c HT&TBYT) assigns CVTH to review and compile for reporting to the Department leadership for consideration and permission for prior processing if the dossier falls into one of the cases prescribed in Clause 21 Article 147 of Decree No. 96/2023/N■-CP.

Time for review and processing: Within 10 working days from the date of receipt of the written request from the organization/individual (TC,CN). In case priority processing is not permitted, the Department of Infrastructure and Medical Devices (C■c HT&TBYT) shall issue a written response to the organization/individual (TC,CN) requesting supplementation of documents because the priority dossier does not yet satisfy the prescribed conditions.

5.8.2. Process flowchart and explanation of implementation steps

s* Process flowchart

Time

for

Step

Implementation Implementing sequence implementation

(No. of

working

days) _|

n Organizations/

Submit written request for priority

individuals processing in advance together with supporting 3.821 | Various
(TC,CN) documents corresponding to the request working
days

T — †—

Receive the written request, submit to the leadership sg22 | 1/4

Department Records Office of the Department of Infrastructure and Medical Devices for assignment _-- day

1 = r |

Leadership of Assign CVTH to compile the list 5823 1/4

Registration Division of dossiers requested for priority processing x day |

+ - —†

CVTH compiles and submits to the leadership of the Registration Division for
assignment of specialists and seconded officials of the

CVTH office to check the conditions for priority processing in advance || "#24 | 1 day
as prescribed

Specialists, - † §

seconded officials Check and send results to CVTH 5.8.2.5 | 2 days

—§

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CVTH reports to the Leadership

CVTH, of the Registration Division, submits to the Deputy Director

Leadership ' . RenH D■N

g on the results of review of priority-processing conditions `

Registration for prior handling 1 day

Division, condition ■

Deputy Director m■o ■

tr■n/ → Department Director

■ If the Deputy Director does not agree 8

does not agree Move specialist to step Š8.2.

CVTH reports to the leadership of the Registration Division

for submission to the Department Director:

CVTH. ~ - List of dossiers not eligible for priority processing

in advance

Leadership - List of eligible dossiers: Review f s§27 | 1 day

Registration and provide leadership direction for the list of each gáy

Division, dossiers eligible for priority processing

Department Director eligible for priority processing

agrees:

Transfer to

5.8.2.6

N For dossiers not eligible for priority processing

` in advance as prescribed

CVTH,

Leadership CVTH reports to the leadership of the Registration Division and submits to the Deputy Director

Registration Division, for signature of the official letter replying to the applicant 5.8.2.8 | 1 day

Deputy Director |

VT C■c Issue the reply letter and 1/2

CBTN send to the applicant 5.8.2.0 day

B For dossiers eligible for priority processing in advance

` as prescribed

1/2

Leadership Review and assign CVTH for processing | m=

of the Department 5.8.2.10 | "84

HT&TBYT ■

Implement the direction of the

Department Director regarding the

CVTH review contents of the priority dossier 5.8.2.11 | 1 day

3x

— Page 30 —

30

T —

CVTH. Leadership CVTH reports to the leadership

of the Registration Division and submits to the Deputy Director

■ for assignment of processing of the priority dossier 1.5

Fm and signature of the official notice 2:8:2-12 || days

to the software management unit

Director software management unit =

If the Deputy Director does not agree:

If agreed, return to step 5.8.2.12

Issue official letter notifying

CVTH, the software system on priority dossier 1/2

? handling assignment in the software 5.8.2.13 | day

VT C■c module

s* Explanation of implementation steps

3.8.2.1. The organization/individual (TC,CN) sends a written request together with supporting documents requesting priority processing of the dossier in accordance with Clause 21 Article 147 of Decree No. 96/2023/N■-CP.

3.8.2.2. The Department Records Office (VT C■c) receives the written request and submits it

to the leadership of the Department of Infrastructure and Medical Devices (C■c HT&TBYT) for assignment of handling.

5.8.2.3. The leadership of the Department of Infrastructure and Medical Devices (C■c HT&TBYT) assigns CVTH to compile the list of dossiers requested for priority processing.

5.8.2.4. After receiving the written request together with supporting documents from the organization/individual (TC,CN) requesting priority processing of the dossier in accordance with Clause 21 Article 147 of Decree No. 96/2023/N■-CP, CVTH compiles and submits to the leadership of the Registration Division (P.■KKD) for assignment of specialists and seconded officials of the office to inspect the conditions for priority processing in advance in accordance with regulations.

5.8.2.5. Specialists and seconded officials inspect the conditions for priority processing in advance for dossiers assigned by the leadership of the Registration Division (P.■KKD) and send the results to CVTH (eligible for priority processing in advance under which provision, or the reasons for ineligibility for priority processing in advance).

5.8.2.6. CVTH reports to the leadership of the Registration Division (P. ■KKD), and submits to the Deputy Director the results of review of the conditions for priority processing in advance.

- In case the Deputy Director does not agree: the Deputy Director returns it for specialists and seconded officials to re-review and reconsider the priority conditions (return to step 5.8.2.5).

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- In case the Deputy Director General agrees: the Deputy Director General reassigns it so that the CV TH reports to the leadership of the Business Registration Division (P. ■KKD) and submits it to the Director General for review and approval of the List in accordance with regulations (move to step 5.8.2.7).

5.8.2.7. The CV TH reports to the leadership of the Business Registration Division (P. ■KKD), and submits to the Director General the results of the review of eligibility for priority processing.

- In case the Director General does not agree: the Director General returns it for re-review and reconsideration of the priority conditions (move to step 5.8.2.6).

- In case the Director General agrees:

+ For the list of dossiers not eligible for priority processing: the Director General returns it so that the CV TH submits it to the Deputy Director General for signing an official reply letter to the organization/individual (TC,CN) (move to step 5.8.2.8).

+ For the list of dossiers eligible for priority processing: the Director General reviews and provides directing opinions on dossiers eligible for priority processing in accordance with regulations (move to step 5.8.2.10).

3.8.2.8. The CV TH reports to the leadership of the Business Registration Division (P. ■KKD) and submits to the Deputy Director General for signing the official reply letter to the organization/individual (TC,CN).

3.8.2.9. The Office of the Department (VT C■c) issues the official reply letter, and the document/archive officer (CBTN) sends it to the organization/individual (TC,CN) in accordance with regulations. '

3.8.2.1. After the Director General has reviewed and provided directing opinions, the leadership of C■c HT&TBYT (Department of Infrastructure and Medical Devices) assigns the CV TH to process and implement the Director General's directing opinions in accordance with regulations.

5.8.2.11. The CV TH processes and implements the Director General's directing opinions on the list of dossiers eligible for priority processing in accordance with regulations as follows:

- In case the Director General does not agree with the list of dossiers eligible for priority processing: the CV TH reassigns it to the specialist/seconded civil servant to re-review and reconsider the priority conditions (move to step 5.8.2.3).

- In case the Director General agrees with the results of the review of eligibility for priority processing: the CV TH reports to the leadership of the Business Registration Division (P. ■KKD) and submits to the Deputy Director General for assignment of processing of the priority dossier and for signing an official letter notifying the software management unit (move to step 5.8.2.13).

3.8.2.12. The CV TH reports to the leadership of the Business Registration Division (P. ■KKD) and submits to the Deputy Director General for assignment of processing of the priority dossier and for signing an official letter notifying the software management unit to change the status to priority and assign the dossier on the system.

5.8.2.13. The CV TH forwards the notification letter so that the system assigns the priority dossier for processing in accordance with item 5.1.3.

4#»

5.8.3. The CV TH and specialists/seconded civil servants shall inspect cases eligible for priority dossier processing in accordance with regulations:

| No. | Priority case | Official request for priority dossier processing and supporting documents | Inspection requirements |

|---|---|---|---|

| | Priority processing may be granted for dossiers falling under one of the following cases: | |

| 1 | Medical devices manufactured domestically | There is an official request for priority dossier processing; which includes information on the dossier code (mã HS). | Inspect the dossier: 1. It is a base dossier submitted into the domestically manufactured medical device stream. 2. The application for issuance of the circulation number for the base medical device has declared information on the domestic manufacturing establishment. |

| 2 | Imported medical devices for which an application dossier for an import license had been submitted to the Ministry of Health (B■ Y t■) before 01/01/2022 but an import license had not yet been granted, and for which a dossier for issuance of a certificate of registration for circulation of imported medical devices has been submitted. | There is an official request for priority dossier processing for registration for circulation number issuance (■KLH) by the entity that submitted the dossier for issuance of an import license for medical devices to the Ministry of Health before 01/01/2022 but was not yet granted the import license; which includes information on the dossier code and the dossier code of the import license application. | 1. The application dossier for issuance of the import license had been submitted and is pending processing results from the Ministry of Health in accordance with regulations. 2. Inspect the dossier: The application for issuance of the circulation number for the medical device: - Has the product type consistent with the information in the import license application dossier. - The establishment name is consistent with the name of the entity that submitted the dossier for issuance of the medical device import license. - In case the Import Order/Official request for issuance of the medical device import license submitted before 01/01/2022 contains information on product code or packaging specification, such information must be consistent with the information in the application for issuance of the circulation number for the medical device. |

| 3 | Chemicals/preparations with the sole purpose of disinfecting medical devices | There is an official request for priority dossier processing; which includes information on the dossier code. | Inspect the dossier: The product is a

chemical/preparation with the sole purpose of disinfecting medical devices, based on the Instructions for Use and Technical Documents. |

| 4 | Medical devices for implementation of new techniques/new methods officially approved by the Ministry of Health for application in medical examination and treatment, but not yet granted a circulation number in Việt Nam | 1. There is an official request for priority dossier processing; which includes information on the dossier code. 2. A document issued by the Ministry of Health officially approving application of the new technique/new method in medical examination and treatment. | Inspect the dossier: Medical device information is consistent with the information in the document by which the Ministry of Health officially approved application of the new technique/new method in medical examination and treatment. |

41-

STT	Trạng h p ưu tiên	Vấn b n ngh ưu tiên x lý HS và Tài li u ch ng minh	Yêu c u ki m tra

| | b n cho phép áp d ng chính th c nh ng ch a c c p s u hành t i Việt Nam; | trong khám b nh ch a b nh |

| 5 | Medical devices with no change in information on product type or product code in the import license or decision granting registration circulation number or certificate of registration for circulation already issued and still valid, but falling under one of the following cases: | | |

| 5.1 | - Change of importing establishment or circulation registration entity; | 1. There is an official request for priority dossier processing; which includes information on the dossier code. 2. The import license or decision granting registration circulation number or certificate of registration for circulation already issued is still valid. 3. A document from the medical device owner regarding the change of importing establishment or circulation registration entity, with confirmation by the establishment. | Inspect the dossier: 1. The application for issuance of the circulation number for the medical device has product type and product code (if any) consistent with the information on the still-valid import license or decision granting registration circulation number or certificate of registration for circulation already issued. 2. Information on the establishment in the application for issuance of the circulation number for the medical device must be consistent with the information in the document from the medical device owner regarding the change of importing establishment or circulation registration entity. |

| 5.2 | - Change of the name of the manufacturing establishment but no change of the manufacturing establishment's address; | 1. There is an official request for priority dossier processing; which includes information on the dossier code. 2. The import license or decision granting registration circulation number or certificate of registration for circulation already issued is still valid. 3. A document from the medical device owner regarding the change of the name of the manufacturing establishment but no change of the manufacturing establishment's address, with confirmation by the establishment. | Inspect the dossier: 1. The application for issuance of the circulation number for the medical device has product type and product code (if any) consistent with the information on the still-valid import license or decision granting registration circulation number or certificate of registration for circulation already issued. 2. Information on the manufacturing establishment in the application for issuance of the circulation number for the medical device must be consistent with the information in the document from the medical device owner regarding the change of the name of the manufacturing establishment but no change of address. |

| 5.3. | - Change of the name of the medical device owner but no change of the medical device owner's address; | 1. There is an official request for priority dossier processing; which includes information on the dossier code. 2. The import license or decision granting registration circulation number or certificate of registration for circulation already issued is still valid. | Inspect the dossier: 1. The application for issuance of the circulation number for the medical device has product type and product code (if any) consistent with the information on the import license or |

STT	Trạng h p u tiên	V n b n ngh u tiên x lý HS và Tài li u ch ng m nh	'Yêu c u ki m tra

| | | certificate of registration for circulation already issued and still valid. 3. A document from the medical device owner regarding the change of the name of the medical device owner but no change of the medical device owner's address, with confirmation by the establishment. | decision granting registration circulation number or certificate of registration for circulation already issued and still valid. 2. Information on the medical device owner in the application for issuance of the circulation number for the medical device must be consistent with the information in the document from the medical device owner regarding the change of the name of the medical device owner but no change of the medical device owner's address. |

| 6 | Medical devices with no change in information on product type but with a change in product code because the old product code has been discontinued, as shown on one of the following documents: import license or decision granting registration circulation number or certificate of registration for circulation already issued and still valid; | 1. There is an official request for priority dossier processing; which includes information on the dossier code. 2. The import license or decision granting registration circulation number or certificate of registration for circulation already issued is still valid. 3. A document from the medical device owner regarding no change in information on product type but a change in product code because the old product code has been discontinued, with confirmation by the establishment. | Inspect the dossier: 1. The application for issuance of the circulation number for the medical device has product type consistent with the information on the import license or decision granting registration circulation number or certificate of registration for circulation already issued and still valid. 2. Information on product code in the application for issuance of the circulation number for the medical device must be consistent with the information in the document from the medical device owner regarding no change in information on product type but a change in product code because the old product code has been discontinued. |

| 7 | Dossiers for which there had previously been a request-for-supplement document or refusal-of-license document issued by the Ministry of Health, where the content of the document only relates to the requirement to update the validity of one of the following documents: authorization letter of the medical device owner, ISO 13485 quality management system certificate, medical device Free Sale Certificate; | 1. There is an official request for priority dossier processing; which includes information on the dossier code. 2. The latest request-for-supplement document or refusal-of-license document of the Ministry of Health, the content of which only relates to the requirement to update the validity of one of the following documents: authorization letter of the medical device owner, ISO 13485 quality management system certificate, medical device Free Sale Certificate. | Inspect the dossier: The latest request-for-supplement document or refusal-of-license document of the Ministry of Health, the content of which only relates to the requirement to update the validity of one of the following documents: authorization letter of the medical device owner, ISO 13485 quality management system certificate, medical device Free Sale Certificate. |

STT	Trạng h p u tiên	V n b n ngh u tiên x lý HS và Tài li u ch ng minh	'Yêu c u ki m tra

| 8 | Dossiers for which there had previously been a request-for-supplement document or refusal-of-license document issued by the Ministry of Health, where the content of the document only requires amendment/supplementation of the name of the medical device. | 1. There is an official request for priority dossier processing; which includes information on the dossier code. 2. The latest request-for-supplement document or refusal-of-license document of the Ministry of Health, the content of which only requires amendment/supplementation of the name of the medical device. | Inspect the dossier: The latest request-for-supplement document or refusal-of-license document of the Ministry of Health, the content of which only requires amendment/supplementation of the name of the medical device. |

5.9. Regulations on the number of appraisal officers (CV T) and dossier appraisal experts:

Before submission to the Council (H■), all dossiers must have comments and assessment opinions from the appraisal officer(s)/appraisal experts. Specifically as follows:

5.9.1. For the procedure for new issuance of circulation numbers for Class C and D medical devices

3.9.1.1. Dossiers falling under one of the cases: (i) expedited issuance, (ii) emergency issuance, including:

- 01 appraisal officer (CV T■).

- 01 member of the appraisal review team before the appraisal review team meeting: being another appraisal officer (CV T■) or a legal expert.

5.9.1.2. Dossiers falling under one of the cases: (i) having a corresponding national technical regulation, (ii) being measuring instruments requiring type approval under the law on measurement

(1). For general medical devices and in vitro diagnostic medical devices that are not reagents, calibrators, and control materials:

- 01 appraisal officer (CV T■), 01 technical expert. Particularly for invasive medical devices related to the central circulatory system and the central nervous system containing medicinal substances, and domestically manufactured medical devices: 01 appraisal officer (CV T■), 01 technical expert, and 01 clinical expert.

- 01 member of the appraisal review team before the appraisal review team meeting: being another appraisal officer (CV T■) or a legal expert.

(2). For in vitro diagnostic medical devices that are reagents, calibrators, and in vitro control materials:

- 01 appraisal officer (CV T■), 02 technical experts (reagents, calibrators, in vitro control materials) and 02 clinical experts.

- 01 member of the appraisal review team before the appraisal review team meeting: being another appraisal officer (CV T■) or a legal expert.

(3) For in vitro diagnostic medical devices submitted via the system:

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- 01 appraisal officer, 01 technical expert (testing machine/equipment), 02 technical experts (reagents, calibrators, in vitro control materials) and 02 clinical experts.

- 01 member of the appraisal review team prior to the review team meeting: being another appraisal officer or a legal expert.

3.9.1.3. Dossiers falling under the case of: other medical devices (not falling under the cases in Sections 5.9.1.1, 5.9.1.2)

(1: For dossiers submitted before 01/01/2024:

a. For general medical devices and in vitro diagnostic medical devices that are not reagents, calibrators, and control materials:

- 01 appraisal officer, 01 technical expert. Particularly for invasive medical devices related to the central circulatory system and the central nervous system containing drugs, and domestically manufactured medical devices: 01 appraisal officer, 01 technical expert and 01 clinical expert.

- 01 member of the appraisal review team prior to the review team meeting: being another appraisal officer or a legal expert.

b. For in vitro diagnostic medical devices being reagents, calibrators, in vitro control materials:

- 01 appraisal officer, 02 technical experts (reagents, calibrators, in vitro control materials) and 02 clinical experts.

~ 01 member of the appraisal review team prior to the review team meeting: being another appraisal officer or a legal expert.

c. For in vitro diagnostic medical devices submitted by system:

- 01 appraisal officer, 01 technical expert (testing machine/equipment), 02 technical experts (reagents, calibrators, in vitro control materials) and 02 clinical experts.

~ 01 member of the appraisal review team prior to the review team meeting: being another appraisal officer or a legal expert.

(2). For dossiers submitted from 01/01/2024:

- 01 appraisal officer.

- 01 member of the appraisal review team prior to the review team meeting: being another appraisal officer or a legal expert.

5.9.2. For the post-market appraisal process for dossiers already having circulation numbers (falling under one of the following cases: (1) expedited issuance, (ii) emergency issuance):

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5.9.2.1. For general medical devices and in vitro diagnostic medical devices that are not reagents, calibrators and control materials: 01 appraisal officer, 01 technical expert. Particularly for invasive medical devices related to the central circulatory system and the central nervous system containing drugs, and domestically manufactured medical devices: 01 appraisal officer, 02 experts (01 technical expert and 01 clinical expert).

5.9.2.2. For in vitro diagnostic medical devices being reagents, calibrators, in vitro control materials: 01 appraisal officer, 04 experts (02 technical experts (reagents, calibrators, in vitro control materials) and 02 clinical experts).

5.9.2.3. For in vitro diagnostic medical devices submitted by system: 01 appraisal officer,

05 experts (01 technical expert (testing machine/equipment), 02 technical experts (reagents, calibrators, in vitro control materials) and 02 clinical experts).

5.10. Description of the steps in the process for issuance of circulation numbers for Class C and D medical devices

5.10.1. Part I: Submission of dossiers and confirmation of fee payment

3.10.1.1. Submission of dossiers

Organizations/individuals submit dossiers online on the system.

\$.10.1.2. Review and receipt of dossiers

Receiving officers of C■c HT&TBYT (Department of Infrastructure and Medical Device Administration) review the dossier components in accordance with Article 30 of Decree No. 98/2021/N■-CP:

- For dossiers with all dossier components fully submitted as prescribed: the receiving officer shall request the organization/individual to pay fees as prescribed.

- For dossiers without all dossier components fully submitted as prescribed: the receiving officer shall notify the organization/individual to submit all dossier components and must clearly state the reason.

Receiving time: From Monday to Friday weekly. Based on the number of dossiers registered for submission by organizations/individuals, C■c HT&TBYT shall arrange personnel for dossier receipt.

The Director of C■c HT&TBYT is assigned to promulgate the process for receipt and review of dossiers at the receiving section of C■c HT&TBYT in compliance with regulations.

3.10.1.3. Fee payment

Organizations/individuals pay fees as prescribed.

3.10.1.4. Confirmation of fee payment

The accounting section shall confirm the appraisal fee for dossiers requesting issuance of medical device circulation numbers in accordance with regulations.

- For dossiers for which fees have been fully paid as prescribed: the accounting section shall confirm full receipt of fees, notify the organization/individual, and the dossier shall be accepted by the system.

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- For dossiers for which fees have not been fully paid as prescribed: the accounting section shall notify the organization/individual to supplement and complete the fee payment procedures.

~ Time for fee confirmation: From Monday to Friday weekly (except for urgent cases of epidemic prevention and control, remediation of consequences of natural disasters or catastrophes).

5.10.2. Part II: Receipt, appraisal and notification of dossier appraisal results

5.10.2.1. Receipt and assignment for dossier appraisal processing

The system shall receive dossiers for which fee payment has been confirmed and shall automatically assign dossiers according to the principles stated in Section 5.1.3 and according to the procedures in Section 5.4, Section 5.5 and Section 5.6.

Based on the number of experts specified in Section 5.9, the appraisal unit shall transfer dossiers to technical and clinical experts for dossier appraisal.

5.10.2.2. Dossier appraisal

The lead appraisal officer is responsible for appraising the dossier and monitoring and expediting the appraisal progress of the appraisal unit.

The appraisal officer and experts shall appraise dossiers in accordance with Decree No. 98/2021/N■-CP and Decree No. 07/2023/N■-CP.

Dossier appraisal timelines:

- New issuance as prescribed in Section 5.4: 08 days.
- New issuance as prescribed in Section 5.5: 01 day.
- New issuance as prescribed in Section 5.6: 15 days.

5.10.2.3. Notification of dossier appraisal results

(1. For dossiers falling under one of the following cases: (i) medical devices having national technical regulations; (ii) measuring instruments requiring pattern approval in accordance with the law on measurement

After obtaining the opinion of the appraisal unit, the appraisal officer is responsible for:

- Appraising the legal dossier.

- Reviewing and consolidating the contents of the appraisal unit's opinion. In case there are differing opinions on the appraisal result between the appraisal officer and the appraisal unit, the lead appraisal officer shall review and may discuss again with the appraisal unit;

- The appraisal officer shall propose to the leadership of C■c HT&TBYT regarding handling contents, specifically as follows:

+ For dossiers appraised as satisfactory or dossiers requiring consultation on contents, the appraisal officer shall transfer them to the list of dossiers meeting appraisal requirements and dossiers requiring consultation so that the synthesizing officer may compile and report to the Head of the Review Team to chair the review meeting and agree on the list of dossiers to be submitted to the Council.

+ For dossiers appraised as unsatisfactory, the appraisal officer shall consolidate the contents requiring supplementation, draft an official letter requesting dossier supplementation and submit it to the leadership of P.■KKD for approval before the Deputy Director signs for issuance. Thereafter, the records office of C■c HT&TBYT shall issue the official letter requesting dossier supplementation on the system.

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„(2 For dossiers: (iv) falling under expedited issuance; (v) falling under emergency issuance

The lead appraisal officer shall appraise the dossier and propose to the leadership of C■c HT&TBYT on the handling contents, specifically as follows:

- For dossiers appraised as satisfactory or dossiers requiring consultation on contents, the appraisal officer shall transfer them to the list of dossiers meeting appraisal requirements and dossiers requiring consultation so that the synthesizing officer may compile and report to the Head of the Review Team to chair the review meeting and agree on the list of dossiers to be submitted to the Council.

- For dossiers appraised as unsatisfactory, the appraisal officer shall consolidate the contents requiring supplementation, draft an official letter requesting dossier supplementation and submit it to the leadership of P.■KKD for approval before the Deputy Director signs for issuance. Thereafter, the records office of C■c HT&TBYT shall issue the official letter requesting dossier supplementation on the system.

(3). For dossiers falling under the case of: other medical devices as prescribed in Clause 5 Article 30 of Decree No. 98/2021/N■-CP

The appraisal officer is responsible for:

- Appraising the legal dossier.

- Reviewing and consolidating the contents of the appraisal unit's opinions for dossiers submitted before 01/01/2024. In case there are differing opinions on the appraisal result between the appraisal officer and the appraisal unit, the appraisal officer shall review and may discuss again with the appraisal unit;

- The lead appraisal officer shall propose to the leadership of C■c HT&TBYT regarding handling contents, specifically as follows:

+ For dossiers appraised as satisfactory or dossiers requiring consultation on contents, the lead appraisal officer shall transfer them to the list of dossiers meeting appraisal requirements and dossiers requiring consultation so that the synthesizing officer may compile and report to the Head of the Review Team to chair the review meeting and unify the list of dossiers to be submitted to the Council.

+ For dossiers appraised as unsatisfactory, the appraisal officer shall consolidate the contents requiring supplementation, draft an official letter requesting dossier supplementation and submit it to the leadership of P.■KKD

for approval before the Deputy Director signs for issuance. Thereafter, the records office of C■c HT&TBYT shall issue the official letter requesting dossier supplementation on the system.

5.10.3. Part III: Appraisal and notification of appraisal results for supplemented dossiers

5.10.3.1. Submission of supplemented dossiers

Organizations/individuals submit supplemented dossiers on the system.

5.10.3.2. Assignment for appraisal processing

(1. For dossiers falling under one of the following cases: (i) medical devices having national technical regulations; (ii) measuring instruments requiring pattern approval in accordance with the law on measurement; (iii) other medical devices as prescribed in Clause 5 Article 30 of Decree No. 98/2021/N■-CP

- The system shall receive supplemented dossiers from organizations/individuals and automatically transfer them to the appraisal officer and appraisal unit that were assigned by the system to appraise the dossier.

- Based on the number of experts specified in Section 5.9, the appraisal unit shall transfer dossiers to technical and clinical experts for dossier appraisal.

(2) For dossiers: (iv) falling under expedited issuance; (v) falling under emergency issuance.

„ The system shall receive supplemented dossiers from organizations/individuals and automatically transfer them to the appraisal officer. Thereafter, the system shall automatically assign the dossier according to the principles stated in Section 5.1.3.

5.10.3.3. Dossier appraisal

The lead appraisal officer is responsible for appraising the dossier and monitoring and expediting the appraisal progress of experts and the appraisal unit.

The appraisal officer and experts shall appraise dossiers in accordance with Decree No. 98/2021/N■-CP and Decree No. 07/2023/N■-CP.

Dossier appraisal timelines:

_ New issuance as prescribed in Section 5.4: 08 days.

- New issuance as prescribed in Section 5.5: 01 day.

- New issuance as prescribed in Section 5.6: 15 days.

5.10.3.4. Notification of appraisal results for supplemented dossiers

(1. For dossiers falling under one of the following cases: (i) medical devices having national technical regulations; (ii) measuring instruments requiring pattern approval in accordance with the law on measurement

After obtaining the opinion of the appraisal unit, the appraisal officer is responsible for:

- Appraising the legal dossier.

- Reviewing and consolidating the contents of the appraisal unit's opinion.

- In case there are differing opinions on the appraisal result between the appraisal officer and the appraisal unit, the appraisal officer shall review and may discuss again with the appraisal unit;

- The appraisal officer shall propose to the leadership of C■c HT&TBYT regarding handling contents, specifically as follows:

+ For supplemented dossiers appraised as satisfactory or dossiers requiring consultation on contents, the appraisal officer shall transfer them to the list of dossiers meeting appraisal requirements and dossiers requiring consultation so that the synthesizing officer may compile and report to the Head of the Review Team to chair the review meeting and agree on the list of dossiers to be submitted to the Council.

+ For supplemented dossiers from the 1st to the 4th supplementation appraised as unsatisfactory, the appraisal officer shall consolidate the contents requiring supplementation, draft an official letter requesting dossier supplementation and submit it to the leadership

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P.■KKD approves before the Deputy Director signs for approval. Thereafter, the Registry Office of the Department of Infrastructure and Medical Device Administration (C■c HT&TBYT) issues the official letter requesting dossier supplementation on the system.

+ If the supplemented dossier fails appraisal for the 5th time, the Appraisal Officer (CV T■) shall transfer it to the list of dossiers failing to meet appraisal requirements, not continue consideration, so that the Synthesis Officer (CV TH) can consolidate and report to the Leadership of the Department of Infrastructure and Medical Device Administration (C■c HT&TBYT) to chair a review meeting and agree on the list of dossiers to be submitted to the Council (H■).

@ For dossiers: (iv) under the fast-track issuance case; (v) under the emergency issuance case

The Appraisal Officer (CV.T■) appraises the dossier and proposes to the Leadership of C■c HT&TBYT on the handling content, specifically as follows:

+ If the supplemented dossier passes appraisal or the dossier requires consultation on content, CV T■ shall transfer it to the list of dossiers meeting appraisal requirements or dossiers requiring opinions, for CV TH to consolidate and report to the Head of the Review Team to chair the review meeting and agree on the list of dossiers to be submitted to H■.

+ If the supplemented dossier fails appraisal for medical devices under the emergency case: CV T■ shall consolidate the content requiring supplementation, draft the Official Letter requesting dossier supplementation and submit it to the Leadership of P.■KKD for approval before the Deputy Director signs for approval. Thereafter, the Registry Office of C■c HT&TBYT issues the official letter requesting dossier supplementation on the system.

+ If the supplemented dossier fails appraisal for medical devices under the fast-track issuance case:

e If the supplemented dossier fails appraisal for the 1st-2nd supplementation, CV T■ shall consolidate the content requiring supplementation, draft the Official Letter requesting dossier supplementation and submit it to the Leadership of P.■KKD for approval before the Deputy Director signs for approval. Thereafter, the Registry Office of C■c HT&TBYT issues the official letter requesting dossier supplementation on the system.

e If the supplemented dossier fails appraisal for the 3rd supplementation, CV T■ shall transfer it to the list of dossiers failing to meet appraisal requirements, not continue consideration, so that CV TH can consolidate and report to the Leadership of C■c HT&TBYT to chair a review meeting and agree on the list of dossiers to be submitted to H■.

(3). For dossiers falling under the case of: other medical devices as prescribed in Clause 3 Article 30 of Decree No. 98/2021/N■-CP

CV TP is responsible for:

- Appraising the legal dossier.

- Reviewing and consolidating the appraisal opinions of the appraisal unit regarding dossiers submitted before 01/01/2024. In case there are differing opinions on the appraisal result between CV T■ and the appraisal unit, CV T■ shall review and may re-discuss with the appraisal units;

- CV T■ proposes to the Leadership of C■c HT&TBYT on the handling content, specifically as follows:

+ If the supplemented dossier passes appraisal or the dossier requires consultation on content, CV T■ shall transfer it to the list of dossiers meeting appraisal requirements and dossiers requiring opinions for

CV TH to consolidate and report to the Head of the Review Team to chair the review meeting and agree on the list of dossiers to be submitted to H■.

+ If the supplemented dossier fails appraisal for the 1st-4th supplementation, CV T■ shall consolidate the content requiring supplementation, draft the Official Letter requesting dossier supplementation and submit it to the Leadership of P.■KKD for approval before the Deputy Director signs for approval. Thereafter, the Registry Office of C■c HT&TBYT issues the official letter requesting dossier supplementation on the system.

+ If the supplemented dossier fails appraisal for the 5th supplementation, CV T■ shall transfer it to the list of dossiers failing to meet appraisal requirements, not continue consideration, so that CV TH can consolidate and report to the Leadership of C■c HT&TBYT to chair a review meeting and agree on the list of dossiers to be submitted to H■.

5.10.4. Part IV: Review Team Meeting

5.10.4.1. Prepare the list of medical devices for the Review Team meeting to report to the Leadership of C■c HT&TBYT for chairing the review meeting and reaching agreement

CV TH consolidates the dossier lists that have been transferred by the appraisal officers (CV T■) after appraisal, including the list of dossiers meeting appraisal requirements, the list of dossiers requiring opinions, and the list of dossiers failing to meet appraisal requirements and not continuing to be considered, in order to report to the Head of the Review Team.

Based on the list reported by CV TH, the Head of the Review Team or the System shall assign one additional member of the Review Team to re-appraise the legal dossier and review the appraisal results of the technical dossier and clinical dossier of the appraisal unit (if any).

The Head of the Review Team shall chair, or authorize the Deputy Head of the Review Team to chair, the meeting to agree on the list to be submitted to H■. Based on the opinions of the members attending the meeting, the Head of the Review Team concludes:

- For dossiers agreed to be submitted to the Director: CV TH shall consolidate the lists (list of dossiers appraised as meeting requirements, list of dossiers appraised as not meeting requirements and not continuing to be considered) and the content for which H■ opinions are required (if any).

- For dossiers proposed for re-consideration: CV TH shall return the dossier to CV T■ for re-review of the explanation, or for re-consultation with the appraisal unit, or for consolidation of the content requiring supplementation.

- For dossiers proposed for re-consideration of the medical device classification result, based on the unanimous opinion of the Review Team, CV TH is responsible for seeking opinions from the Classification Team; at the same time, the dossier shall be returned to CV T■. After receiving the opinion of the Classification Team, CV TH shall forward such opinion to CV T■ for attachment of the Classification Team's opinion to the dossier and reporting at the nearest Review Team meeting.

. Members attending the meeting shall agree on the meeting contents and sign the minutes of the Review Team meeting.

5.10.4.2. Send the list of medical devices to be submitted to H■

! Supplemented dossiers failing appraisal at the 1st-2nd supplementation for other dossiers submitted before 01/01/2024

? Supplemented dossiers failing appraisal at the 3rd supplementation for other dossiers submitted before 01/01/2024

Based on the Minutes of the review meeting agreeing on the list of dossiers to be submitted to H■, the Director shall consider the quantity and content requiring H■ opinions:

- For dossiers agreed to be submitted to H■: CV TH shall consolidate the lists (list of dossiers appraised as meeting requirements, list of dossiers appraised as not meeting requirements and not continuing to be considered) and the content requiring H■ opinions (if any). Thereafter, CV TH reports to the Department Leadership to issue a written document sending the dossier lists to H■.

- For dossiers proposed for re-consideration, the Department Leadership shall return the dossiers to CV T■ for review of the explanation or for re-consultation with the appraisal unit or for consolidation of the content requiring supplementation.

5.10.5. Part V: Submission to H■

5.10.5.1. Prepare the list of medical devices submitted by C■c HT&TBYT to H■

Based on the list and the content for which H■ opinions are sought (if any) from C■c HT&TBYT, the Head of the H■ Secretariat Team is responsible for preparing the list of dossiers for reporting to the Chairperson to request a meeting schedule and the list to be submitted to H■, and for sending them to H■ members before the H■ meeting.

Time for sending dossiers to H■ members before the H■ meeting:

- New issuance as prescribed in Section 5.4 and 5.6: 05 days.

- New issuance as prescribed in Section 5.5: 01 day.

5.10.5.2. H■ meeting

Based on the dossiers sent by the H■ Secretary, H■ members shall review and provide opinions on the issuance of circulation registration numbers (SLH) for each dossier.

At the end of the meeting, the H■ Secretary is responsible for finalizing the Minutes together with the list of dossiers approved by H■, not approved, requiring supplementation, or requiring additional opinions, and submitting them to the H■ Chairperson and H■ members for review and approval of the H■ meeting minutes.

5.10.5.3. Submit to the H■ Chairperson for approval of H■ meeting results

The H■ Chairperson shall review and approve the contents of the minutes and the H■ meeting results:

- Cases agreeing to grant or not grant circulation numbers.

- Cases requiring supplementation or explanation: approve the contents requiring supplementation/explanation so that organizations and individuals (TC,CN) can supplement and complete the dossier.

- Cases requiring additional opinions from relevant Departments/Bureaus/units.

The Head of the H■ Secretariat Team shall send the conclusions to C■c HT&TBYT: the H■ Minutes and the list of dossiers approved by H■, not approved, requiring supplementation, or requiring additional opinions.

5.10.6. Part VI: Completion of procedures for issuance of SLH

5.10.6.1. C■c HT&TBYT implements the conclusions of H■

Based on the conclusions of H■, the Deputy Director shall consider:

(1). Dossiers proposed for issuance of circulation numbers or non-issuance of circulation numbers:

- Assign CV T■ to draft the Certificate of Medical Device Circulation Registration, print the dossier, initial it, and send it to CV TH for submission to the Leadership of P.■KKD and the Deputy Director for approval before submission to the Director for consideration and signature approval of the Certificate of Medical Device Circulation Registration.

- Assign CV TH to draft the Submission Sheet, the Decision on issuance of SLH, and the Decision on discontinuation of consideration of SLH for submission to the Director for consideration and signature. In particular, for dossiers proposed for issuance of SLH, CV TH shall note to review the validity period of documents and consider separating dossiers with documents about to expire together with dossiers of similar products for prior submission to the Director in order to ensure fairness, transparency, and that the documents remain valid at the time of issuance of SLH.

- CV T■ may seek opinions again from the Review Team and the Medical Device Classification Team in cases where CV T■ and the appraisal unit have not yet reached consensus with the opinions and requirements of H■.

(2). Dossiers requiring supplementation/explanation:

Assign CV T■ to consider:

- Consolidating the content requiring supplementation, drafting the Official Letter requesting dossier supplementation, and submitting it to the Leadership of P.■KKD for approval before the Deputy Director signs for approval.

Thereafter, the Registry Office of C■c HT&TBYT issues the official letter requesting dossier supplementation on the system.

- Seeking the opinion of the Review Team again in cases where CV T■ and the appraisal unit have not yet reached consensus with the opinions and requirements of H■.

For dossiers for which the Council requires supplementation/explanation but the dossier has exhausted the permitted number of supplementations: CV T■ shall re-consider the dossier and seek the opinion of the Review Team on discontinuing consideration of SLH or granting SLH.

(3). Dossiers proposed for seeking additional opinions from relevant Departments/Bureaus/units: CV TH shall submit to the Department Leadership a written request for opinions from relevant Departments/Bureaus/units; at the same time, the dossier shall be returned to CV T■. After receiving opinions from the relevant Departments/Bureaus/units, CV TH shall forward such opinions to CV T■ for attachment of the opinions of the relevant Departments/Bureaus/units to the dossier and reporting at the nearest Review Team meeting.

5.10.6.2. Director signs approval for issuance of SLH

The Director shall consider and sign for approval:

- The Submission Sheet of the list of medical devices for issuance of SLH or discontinuation of consideration of SLH, together with the Decision on issuance of SLH and the Decision on discontinuation of consideration of SLH.

- The Certificate of Medical Device Circulation Registration.

5.10.6.3. Issue the Certificate of Circulation Registration

The Department Registry Office shall issue the Decision and the Certificate of Medical Device Circulation Registration.

5.10.7. Part VII. Appraisal of certain documents updated by organizations and individuals during dossier processing

5.10.7.1. Appraisal of legal documents

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During dossier processing, if the legal documents prescribed in Article 30 of Decree No. 98/2021/N■-CP expire and the organizations/individuals (TC,CN) submit a written document to C■c HT&TBYT together with legal documents updated for validity in accordance with the requirements and provisions of Decree No. 98/2021/N■-CP and Decree No. 07/2023/N■-CP, the Leadership of C■c HT&TBYT (or the System) shall assign CV T■ to appraise and process the dossier according to the steps stated above.

5.10.7.2. Appraisal of documents related to changes in information of organizations/individuals

During dossier processing, if TC,CN submit a written document to C■c HT&TBYT together with documents related to changes in TC,CN information, the Leadership of C■c HT&TBYT (or the System) shall assign CV T■ to appraise and process the dossier according to the steps stated above.

5.11. Description of the steps of the post-market appraisal procedure for dossiers already granted SLH for Class C and D medical devices under the fast-track case and emergency case

5.11.1. Part I: Assignment of dossiers, appraisal of dossiers

5.11.1.1. Assignment for processing post-market appraisal dossiers

Based on the post-market inspection plan approved by the Department Leadership and the dossier list provided by C■c HT&TBYT, the System assigns post-market dossier appraisal to CV TD and the appraisal unit.

For the assignment of CV TD, the following principle applies: the CV TD monitoring and consolidating the post-market appraisal results of the dossier must not be the CV T■ who appraised the dossier that had already been granted SLH.

Based on the number of experts specified in Section 5.9, the appraisal unit shall transfer the dossier to technical and clinical experts for post-market appraisal of the dossier.

5.11.1.2. Dossier appraisal

Time limit for dossier appraisal: 30 days.

CV TD is responsible for monitoring and expediting the dossier appraisal progress of the appraisal unit. During dossier monitoring, if any content related to the legal dossier is identified, CV TD is responsible for consolidating it.

5.11.1.3. Handling of dossier appraisal results

After receiving the opinion of the appraisal unit, CV TD is responsible for:

- Reviewing and consolidating the appraisal opinions of the appraisal unit and the content related to the legal dossier (if any);
- In case there are differing opinions on the appraisal result between CV TD and the appraisal unit, CV TD shall review and may re-discuss with the appraisal unit;
- For dossiers for which appraisal results have been agreed upon, CV TD proposes to the Leadership of C■c HT&TBYT on the handling content, specifically as follows:
 - + If the post-market dossier meets requirements, CV TD shall transfer the dossier so that CV TH can consolidate the list of post-market dossiers meeting requirements and submit the post-market appraisal results to the Director.
 - + If the post-market dossier does not meet requirements, CV TD shall transfer the dossier so that CV TH can consolidate the list of post-market dossiers not meeting requirements and report to the Leadership of C■c HT&TBYT:

e Work with TC,CN and consider the clarification/explanation provided by TC,CN.

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s_ Reach agreement on whether the post-market inspection dossier (HS h■u ki■m) meets requirements or does not meet requirements.

5.11.2. Part II: Submission to the Council (H■)

3.1.2.1. Prepare the list of medical devices (TBYT) for submission to the Council (H■) and report to the leadership of the Department

HT&TBVT shall take the lead in convening a review meeting to examine and reach consensus.

The general affairs officer (CV TH) shall compile the list of post-market inspection dossiers that do not meet requirements in order to report to the leadership of C■c HT&TBYT (Department of Infrastructure and Medical Device Works) - the Head of the Review Team shall chair the meeting to unify the list for submission to the Council (H■). Based on the opinions of members attending the meeting, the leadership of C■c HT&TBYT shall conclude:

- For dossiers agreed to be submitted to the Director of the Department: the general affairs officer (CV TH) shall compile the list of post-market inspection dossiers that do not meet requirements and the issues for which the Council's opinion is to be sought (if any).
- For dossiers proposed for reconsideration: the general affairs officer (CV TH) shall transfer the dossier to the tracking officer (CV TD) for review and re-solicitation of opinions from the appraisal unit.
- For dossiers proposed for reconsideration of the medical device classification result on the basis of the consensus opinion of the Review Team, the general affairs officer (CV TH) is responsible for seeking the opinion of the Classification Team; at the same time, the dossier shall be transferred to the appraisal officer (CV T■). After receiving the opinion of the Classification Team, the general affairs officer (CV TH) shall transfer such opinion to the appraisal officer (CV T■) for attachment of the Classification Team's opinion to the dossier and reporting at the nearest Review Team meeting.

Members attending the meeting shall agree on the meeting contents and sign the minutes of the Review Team meeting.

§.11.2.2. Send the list of medical devices (TBYT) for submission to the Council (H■)

Based on the minutes of the review meeting and the agreed list of dossiers for submission to the Council (H■), the Department leadership shall consider the list of post-market inspection dossiers that do not meet requirements and the issues for which the Council's opinion is to be sought (if any):

- For dossiers agreed to be submitted to the Council (H■): the general affairs officer (CV TH) shall compile the list of post-market inspection dossiers that do not meet requirements and the issues for which the Council's opinion is to be sought (if any). Thereafter, the general affairs officer (CV TH) shall report to the Department leadership for issuance of an official document sending the dossier list to the Council (H■).
- For dossiers proposed for reconsideration, the Department leadership shall transfer the dossier to the tracking officer (CV TD) for review and re-solicitation of opinions from the appraisal unit.

3.11.2.3. Prepare the list of medical devices (TBYT) submitted by C■c HT& TBYT to the Council (H■)

Based on the list submitted by C■c HT&TBYT to the Council (H■), the Head of the Council (H■) Secretariat Team is responsible for preparing the list of dossiers to be reported to the Chairperson for meeting scheduling and the list for submission to the Council (H■) for sending to Council members before the Council meeting.

Time for sending dossiers to Council members before the Council meeting: 05 days.

5.11.2.4. Council meeting

Based on the dossiers sent by the Council Secretary, Council members shall review and provide opinions on the withdrawal of the circulation registration number (SLH) for each dossier.

At the end of the meeting, the Council Secretary is responsible for finalizing the minutes together with the list of medical devices proposed by the Council (H■) for SLH withdrawal and submitting them to the Chairperson of the Council (H■); Council members shall review and approve the minutes of the Council meeting.

5.11.2.5. Submit to the Chairperson of the Council (H■) for approval of the Council meeting results

The Chairperson of the Council (H■) shall approve the contents of the minutes and the results of the Council meeting: the list of circulation registration numbers (SLH) proposed by the Council (H■) for withdrawal.

The Head of the Council Secretariat Team shall send to C■c HT&TBYT the conclusion: the Council (H■) minutes and the list of medical devices (TBYT) proposed by the Council (H■) for SLH withdrawal.

5.11.3. Part II: Finalize procedures for continuation or withdrawal of SLH

5.11.3.1. Deputy Director implements the Council's conclusion

Based on the Council's conclusion, the Deputy Director shall consider the Council's conclusion:

- For the SLH proposed by the Council (H■) for withdrawal: transfer to the general affairs officer (CV TH) for drafting the Submission Note (T■ trình) and the Decision on withdrawal of SLH for submission to the leadership of P.■KKD, and for approval by the Deputy Director before submission to the Director for consideration and signature.

- The general affairs officer (CV TH) shall submit to the leadership of P.■KKD and the Deputy Director for approval before submission to the Director for consideration and signature the post-market inspection results dossier together with: the list of dossiers that passed post-market inspection, the list of dossiers that failed post-market inspection and were submitted for reporting to the Council (H■), and the Decision on withdrawal of SLH.

5.11.3.2. Issue the Decision on withdrawal of SLH and carry out SLH withdrawal on the system

The Department's clerical unit (VT C■c) shall issue the Decision on withdrawal of SLH.

The tracking officer (CV TD) shall carry out the withdrawal of SLH on the system and publicly disclose it on the electronic information portal.

5.12. Consideration and handling of cases where the Medical Device Circulation Certificate contains errors due to system error:

Where C■c HT&TBYT receives a written request from the organization/individual (TC,CN) regarding errors in the medical device circulation registration certificate, such as information not matching the information declared by the organization/individual (TC,CN) in the application for issuance of the medical device circulation number due to system extraction errors: the leadership of C■c HT&TBYT shall assign the appraisal officer (CV T■) and the general affairs officer (CV TH) to review and report to the leadership of C■c HT&TBYT for consideration of issuance of a replacement Medical Device Circulation Certificate.

6. Dossier for issuance of circulation number

6.1. Types of dossiers

6.1.1. Dossier for medical devices with corresponding national technical regulations

6.1.1.1. Dossier components

a) Application for initial issuance of circulation registration number (SLH) for class C, D medical devices with corresponding national technical regulations, using Form No. 04 prescribed in Appendix I issued together with Thông t■ s■ 44/2025/TT-BYT.

b) Valid ISO 13845 quality management system certificate at the time of dossier submission.

€) Letter of authorization from the medical device owner authorizing the establishment to carry out circulation registration, in the form prescribed in Appendix V issued together with Thông t s 44/2025/TT-BYT, valid at the time of dossier submission, except for the case specified at Point a Clause 1 Article 25 of Ngh s 98/2021/N-CP (Vietnamese enterprises, cooperatives, and household businesses that are owners of the medical device).

d) Certificate of eligibility for warranty service as prescribed in Appendix VI issued together with Thông t s 44/2025/TT-BYT, issued by the medical device owner, except for single-use medical devices according to the owner's specification or where there are documents proving that no warranty regime applies.

■) Valid certificate of free sale/circulation at the time of dossier submission for imported medical devices.

e) Certificate of conformity.

g) Common Submission Dossier Template for medical devices in accordance with ASEAN regulations for dossiers submitted from 01/01/2024.

.h) Certificate of results of clinical trial of medical devices issued by a competent authority in cases where clinical trial is required by law.

j) For dossiers submitted before 01/01/2024:

~ Summary technical description document of the medical device in Vietnamese, enclosed with technical documents describing the functions and technical specifications of the medical device issued by the medical device owner.

For in vitro reagents, calibrators, and control materials only: technical documents in Vietnamese enclosed with documents on raw materials, product safety, product manufacturing process and quality control, clinical and pre-clinical study reports including stability reports.

~ Instructions for use of the medical device.

- Label specimen to be used when circulating the medical device in Vietnam.

(Requirements for certain documents in the dossier for application for initial issuance of circulation number:

The organization/individual (TC,CN) is responsible for: ensuring that the dossier documents and materials remain valid throughout the implementation process (as stipulated in Ngh s 07/2023/N-CP).

a) For the quality management system certificate: submit the original or a certified true copy or a copy certified by the establishment.

. If the quality management system certificate is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be certified in accordance with law.

→) For the letter of authorization from the medical device owner and the certificate confirming the establishment's eligibility for warranty service:

- For domestically manufactured medical devices: submit the original or a certified true copy;

- For imported medical devices: submit a consular legalized copy or a certified true copy of the consular legalized document.

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e) For the certificate of free sale/circulation: submit a consular legalized copy or a certified true copy of the consular legalized document.

If the certificate of free sale/circulation is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be certified in accordance with law.

d) For the certificate of conformity: submit the original or a certified true copy or a copy certified by the establishment.

3) For the CSDT dossier: submit a copy certified by the establishment. If the CSDT dossier is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be certified in accordance with law.

e) For technical documents of the medical device: submit a copy certified by the establishment.

- For the instructions for use of the medical device: submit a Vietnamese version certified by the establishment, enclosed with the original English version issued by the medical device owner for imported medical devices.

- For the label specimen: submit a label specimen copy certified by the establishment. The label specimen must satisfy the requirements prescribed by the law on goods labels.)

6.1.1.2. Number of dossier sets: 01 set

6.1.2. Dossier for medical devices that are measuring instruments subject to pattern approval in accordance with the law on measurement

6.1.2.1. Dossier components

a) Application for initial issuance of circulation registration number (SLH) for class C, D medical devices that are measuring instruments subject to pattern approval in accordance with the law on measurement, using Form No. 05 prescribed in Appendix I issued together with Thông t s 44/2025/TT-BYT.

b) Valid ISO 13845 quality management system certificate at the time of dossier submission.

c) Letter of authorization from the medical device owner authorizing the establishment to carry out circulation registration, in the form prescribed in Appendix V issued together with Thông t s 44/2025/TT-BYT, valid at the time of dossier submission, except for the case specified at Point a Clause 1 Article 25 of Ngh s 98/2021/N-CP (Vietnamese enterprises, cooperatives, and household businesses that are owners of the medical device). I

■) Certificate of eligibility for warranty service as prescribed in Appendix VI issued together with Thông t s 44/2025/TT-BYT, issued by the medical device owner, except for single-use medical devices according to the owner's specification or where there are documents proving that no warranty regime applies.

■) Valid certificate of free sale/circulation at the time of dossier submission for imported medical devices.

e) Pattern approval decision.

8) Common Submission Dossier Template for medical devices in accordance with ASEAN regulations (CSDT dossier) for dossiers submitted from 01/01/2024

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.h) Certificate of results of clinical trial of medical devices issued by a competent authority in cases where clinical trial is required by law.

j) For dossiers submitted before 01/01/2024.

- Summary technical description document of the medical device in Vietnamese, enclosed with technical documents describing the functions and technical specifications of the medical device issued by the medical device owner.

For in vitro reagents, calibrators, and control materials only: technical documents in Vietnamese enclosed with documents on raw materials, product safety, product manufacturing process and product quality control, clinical and pre-clinical study reports including stability reports.

- Instructions for use of the medical device.
- Label specimen to be used when circulating the medical device in Vietnam.

(Requirements for certain documents in the dossier for application for initial issuance of circulation number:

The establishment is responsible for: ensuring that the dossier documents and materials remain valid throughout the implementation process (as stipulated in Nghị quyết số 07/2023/NQ-CP).

a) For the quality management system certificate: submit the original or a certified true copy or a copy certified by the establishment.

If the quality management system certificate is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be certified in accordance with law.

b) For the letter of authorization from the medical device owner and the certificate confirming the establishment's eligibility for warranty service:

- For domestically manufactured medical devices: submit the original or a certified true copy;
- For imported medical devices: submit a consular legalized copy or a certified true copy of the consular legalized document.

©) For the certificate of free sale/circulation: submit a consular legalized copy or a certified true copy of the consular legalized document.

If the certificate of free sale/circulation is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be certified in accordance with law.

d) For the pattern approval decision: submit the original or a certified true copy or a copy certified by the establishment.

ä) For the CSDT dossier: submit a copy certified by the establishment. If the CSDT dossier is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be certified in accordance with law.

e) For technical documents of the medical device: submit a copy certified by the establishment.

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- For the instructions for use of the medical device: Submit a Vietnamese version certified by the establishment, enclosed with the original English version issued by the medical device owner for imported medical devices.

- For the label specimen: Submit a label specimen certified by the establishment. The label specimen must satisfy the requirements prescribed by the laws on goods labeling.)

6.1.2.2. Number of dossiers: 01 set

6.1.3. Dossier under the fast-track issuance case

6.1.3.1. Dossier components

a) Written request for first-time issuance of the circulation number for class C, D medical devices under the fast-track case, using Form No. 06 provided in Appendix I issued together with Circular No. 44/2025/TT-BYT. '

b) Valid ISO 13845 quality management system certificate at the time of dossier submission.

c) Letter of authorization from the medical device owner authorizing the establishment to carry out circulation registration, using the Form provided in Appendix V issued together with Circular No. 44/2025/TT-BYT, valid at the time of dossier submission, except for the case prescribed at Point a Clause 1 Article 25 of Decree No. 98/2021/N■-CP (Vietnamese enterprises, cooperatives, and household businesses that are owners of the medical device).

d) Warranty eligibility certificate as prescribed in Appendix VI issued together with Circular No. 44/2025/TT-BYT, issued by the medical device owner, except for single-use medical devices according to the medical device owner's regulations or where documents are available proving that there is no warranty regime.

■) Marketing authorization/circulation certificate issued by one of the reference countries for the case prescribed at Point a Clause 2 Article 29 of Decree No. 98/2021/N■-CP.

e) Marketing authorization/circulation certificate for imported medical devices and Import License or Circulation Number or Certificate of Circulation Registration for the case prescribed at Point b Clause 2 Article 29 of Decree No. 98/2021/N■-CP.

g) Quality assessment certificate issued by a competent authority of Vietnam for in vitro diagnostic medical devices, except for the following cases:

- Falling under Lists A, B of Appendix 2 of the European In Vitro Diagnostic Medical Devices Directive/Agreement and having been granted a Certificate of Free Sale by one of the EU member states, the UK, or Switzerland;

- Falling under Lists A, B of Appendix 2 of the European In Vitro Diagnostic Medical Devices Directive/Agreement and having been granted a Market Authorization by one of the reference countries;

- Not falling under Lists A, B of Appendix 2 of the European In Vitro Diagnostic Medical Devices Directive/Agreement but having been granted a Market Authorization by one of the reference countries;

~ Included in the list announced by the Minister of Health (B■ Y t■).

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h) ASEAN Common Submission Dossier Template for medical devices (CSDT dossier) for dossiers submitted from 01/01/2024

j) For dossiers submitted before 01/01/2024.

- Vietnamese summary technical description document of the medical device, enclosed with technical documents describing the functions and technical specifications of the medical device issued by the medical device owner.

Particularly for in vitro reagents, calibrators, and control materials: Vietnamese technical documents enclosed with documents on raw materials, product safety, manufacturing process and product quality control, clinical and pre-clinical study reports including stability reports.

- Instructions for use of the medical device.

- Label specimen to be used when circulating the medical device in Vietnam.

(Requirements for certain documents in the dossier:

The establishment is responsible for: Ensuring that the papers and documents in the dossier remain valid throughout the implementation process (as prescribed in Decree No. 07/2023/N■-CP).

a) For the quality management system certificate: Submit the original or a certified true copy or a copy certified by the establishment.

Where the quality management system certificate is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be notarized/authenticated in accordance with law.

b) For the letter of authorization from the medical device owner and the certificate confirming that the establishment is eligible to provide warranty services:

- For domestically manufactured medical devices: Submit the original or a certified true copy;

- For imported medical devices: Submit the consular legalized copy or a certified true copy of the consular legalized copy.

e) For the marketing authorization/circulation certificate: Submit the consular legalized copy or a certified true copy of the consular legalized copy.

Where the marketing authorization/circulation certificate is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be notarized/authenticated in accordance with law.

4) For the quality assessment certificate: Submit the original or a certified true copy or a copy certified by the establishment.

ä) For the CSDT dossier: Submit a copy certified by the establishment. Where the CSDT dossier is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be notarized/authenticated in accordance with law.

e) For technical documents of the medical device: Submit a copy certified by the establishment.

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~ For the instructions for use of the medical device: Submit a Vietnamese version certified by the establishment, enclosed with the original English version issued by the medical device owner for imported medical devices.

- - For the label specimen: Submit a label specimen certified by the establishment. The label specimen must satisfy the requirements prescribed by the laws on goods labeling.)

6.1.3.2. Number of dossiers: 01 set

6.1.4. Dossier for medical devices serving epidemic prevention and control, remediation of consequences of natural disasters and catastrophes in urgent cases

6.1.4.1. Dossier components

a) Written request for first-time issuance of circulation number using Form No. 07 provided in Appendix I issued together with Circular No. 44/2025/TT-BYT.

b) Valid ISO 13845 quality management system certificate at the time of dossier submission.

€) Letter of authorization from the medical device owner authorizing the establishment to carry out circulation registration, using the Form provided in Appendix V issued together with Circular No. 44/2025/TT-BYT, valid at the time of dossier submission, except for the case prescribed at Point a Clause I Article 25 of Decree No. 98/2021/N■-CP (Vietnamese enterprises, cooperatives, and household businesses that are owners of the medical device).

d) Warranty eligibility certificate as prescribed in Appendix VI issued together with Circular No. 44/2025/T T-BYT, issued by the medical device owner, except for single-use medical devices according to the medical device owner's regulations or where documents are available proving that there is no warranty regime.

■) Marketing authorization/circulation certificate or emergency use authorization for imported medical devices.

e) Technology transfer contract for the case prescribed at Point ■ Clause 3 Article 29 of Decree No. 98/2021/N■-CP.

ø) Processing/manufacturing outsourcing contract for the case prescribed at Point e Clause 3 Article 29 of Decree No. 98/2021/N■-CP.

h) Certificate of inspection or product quality assessment issued by one of the entities on the list published on the Ministry of Health (B■ Y t■) Electronic Information Portal if falling under one of the following cases:

-- Domestically manufactured medical devices;

- Medical devices that have been authorized for circulation or emergency use by the competent authority in EU member states, the UK, or Switzerland but are not included in the list of common products published by the European Health Security Committee (Health Security Committee - EUHSC).

ï) ASEAN Common Submission Dossier Template for medical devices for dossiers submitted from 01/01/2024.

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k) Certificate of medical device clinical trial results issued by the competent authority in cases where clinical trials are required by law.

D For dossiers submitted before 01/01/2024.

- Vietnamese summary technical description document of the medical device, enclosed with technical documents describing the functions and technical specifications of the medical device issued by the medical device owner.

Particularly for in vitro reagents, calibrators, and control materials: Vietnamese technical documents enclosed with documents on raw materials, product safety, manufacturing process and product quality control, clinical and pre-clinical study reports including stability reports.

- Instructions for use of the medical device.

~ Label specimen to be used when circulating the medical device in Vietnam.

(Requirements for certain documents in the dossier:

The establishment is responsible for: Ensuring that the papers and documents in the dossier remain valid throughout the implementation process (as prescribed in Decree No. 07/2023/N■-CP).

a) For the quality management system certificate: Submit the original or a certified true copy or a copy certified by the establishment.

. Where the quality management system certificate is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be notarized/authenticated in accordance with law.

→) For the letter of authorization from the owner of the medical device and the certificate confirming that the establishment is eligible to provide warranty services:

- For domestically manufactured medical devices: Submit the original or a certified true copy;

- For imported medical devices: Submit the consular legalized copy or a certified true copy of the consular legalized copy.

Where consular legalization is unavailable, the original must be provided together with confirmation information.

©) For the marketing authorization/circulation certificate: Submit the consular legalized copy or a certified true copy of the consular legalized copy.

Where the marketing authorization/circulation certificate is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be notarized/authenticated in accordance with law.

Where consular legalization is unavailable, the lookup link evidencing circulation/authorization for use of the medical device from the licensing authority's website must be provided, together with a document from the establishment providing information on the lookup link. The licensing information lookup result on the website must include at least the following information in English: name; type/model; manufacturer, country of manufacture.

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D3) For quality assessment certificates, test reports, and evaluation reports: Submit the original or a certified true copy or a copy certified by the establishment.

ä) For the CSDT dossier: Submit a copy certified by the establishment. Where the CSDT dossier is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be notarized/authenticated in accordance with law.

e) For technical documents of the medical device: Submit a copy certified by the establishment.

- For the instructions for use of the medical device: Submit a Vietnamese version certified by the establishment, enclosed with the original English version issued by the medical device owner for imported medical devices.

- For the label specimen: Submit a label specimen certified by the establishment. The label specimen must satisfy the requirements prescribed by the laws on goods labeling.)

6.1.4.2. Number of dossiers: 01 set.

6.1.5. Dossier for other medical devices

6.1.5.1. Dossier components

___a) Written request for first-time issuance of circulation number for other class C, D medical devices, using Form No. 08 provided in Appendix I issued together with Circular No. 44/2025/TT-BYT.

b) Valid ISO 13845 quality management system certificate at the time of dossier submission. "

e) Letter of authorization from the medical device owner authorizing the establishment to carry out circulation registration, using the Form provided in Appendix V issued together with Circular No. 44/2025/TT-BYT, valid at the time of dossier submission, except for the case prescribed at Point a Clause 1 Article 25 of Decree No. 98/2021/N-CP (Vietnamese enterprises, cooperatives, and household businesses that are owners of the medical device).

■) Warranty eligibility certificate as prescribed in Appendix VI issued together with Circular No. 44/2025/T T-BYT, issued by the medical device owner, except for single-use medical devices according to the medical device owner's regulations or where documents are available proving that there is no warranty regime.

■) Valid marketing authorization/circulation certificate at the time of dossier submission for imported medical devices.

e) Result of appraisal of the ASEAN Common Submission Dossier Template for medical devices by an entity designated by the Minister of Health (B Y t) and the CSDT dossier for dossiers submitted from 01/01/2024

g) For dossiers submitted before 01/01/2024.

- Vietnamese summary technical description document of the medical device, enclosed with technical documents describing the functions and technical specifications of the medical device issued by the medical device owner.

Particularly for in vitro reagents, calibrators, and control materials: Vietnamese technical documents enclosed with documents on raw materials, on safety of the

product, manufacturing process and product quality control process, clinical and pre-clinical study reports including stability reports.

- Instructions for use of the medical device.

- Label specimen to be used when circulating in Vietnam for the medical device.

h) For in vitro diagnostic medical devices that are reagents, calibrators, and control materials, there must be an additional certificate of quality issued by a competent authority of Vietnam.

i) For chemicals and preparations having the sole purpose of disinfecting medical devices, there must additionally be a testing slip for composition and content of disinfectant active substances issued by an entity that has publicly declared its eligibility to perform testing in accordance with the law on management of chemicals and insecticidal and bactericidal preparations used in the household and medical sectors; a testing report assessing the biological efficacy of the product and the side effects of the product on trial participants, issued by an entity that has publicly declared its eligibility to perform testing in accordance with the law on management of chemicals and insecticidal and bactericidal preparations used in the household and medical sectors.

k) Certificate of medical device clinical trial results issued by a competent authority in cases where clinical trials are required under law.

(Requirements for certain documents in the dossier:

The establishment is responsible for: ensuring that the papers and documents in the dossier remain valid throughout the implementation process (as stipulated in Decree No. 07/2023/N■-CP).

a) For the certificate of conformity with quality management standards: Submit the original or a certified true copy or a copy certified by the establishment.

. In cases where the certificate of conformity with quality management standards is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be notarized/authenticated in accordance with law.

.) For the authorization letter of the medical device owner and the confirmation document of eligibility for warranty service provision:

- For domestically manufactured medical devices: Submit the original or a certified true copy;

- For imported medical devices: Submit the consular legalized copy or a certified true copy of the consular legalized copy.

©) For the free sale certificate/circulation certificate: Submit the consular legalized copy or a certified true copy of the consular legalized copy.

In cases where the circulation document is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be notarized/authenticated in accordance with law. kL

„3 For quality assessment certificates, testing slips, testing reports, and CSDT dossier appraisal results: Submit the original or a certified true copy or a copy certified by the establishment.

ä) For the CSDT dossier: Submit a copy certified by the establishment. In cases where the CSDT dossier is not in English or Vietnamese, it must be translated into Vietnamese. The translation must be notarized/authenticated in accordance with law.

e) For technical documents of the medical device: Submit a copy certified by the establishment.

- For instructions for use of the medical device: Submit a Vietnamese version certified by the establishment, together with the original English version issued by the medical device owner for imported medical devices.

- For label specimens: Submit a label specimen certified by the establishment. The label specimen must satisfy the requirements under the law on goods labels.)

6.1.5.2. Number of dossiers: 01 set

6.2. Receipt and appraisal of dossiers

„ 6.2.1, Organizations/individuals submit dossiers to the C■c HT&TBYT (Department of Infrastructure and Medical Device Administration) through the electronic information portal for medical device management.

6.2.2. For dossiers of medical devices having corresponding national technical regulations and medical devices that are measuring instruments subject to type approval in accordance with the law on metrology:

a) Where there is no request for amendment or supplementation of the dossier, the C■c HT&TBYT has the responsibility to: organize appraisal for issuance of the circulation number within 30 days from the date of receipt of a complete and valid dossier (including documents confirming payment of the appraisal fee for issuance of the circulation license as prescribed by the Ministry of Finance). In cases where the circulation number is not granted, a written response stating the reason must be issued.

b) Where the dossier is incomplete, the C■c HT&TBYT must notify the organization/individual to supplement and amend the dossier, clearly stating which documents must be supplemented and which contents must be amended, within 25 days from the date of receipt of a complete and valid dossier.

- c) Upon receipt of the request for dossier supplementation and amendment, the organization/individual must supplement and amend in accordance with the notified contents and send it to the C■c HT&TBYT.

_ Where the organization/individual has supplemented and amended the dossier but not in accordance with the request, the C■c HT&TBYT shall notify the organization/individual to continue completing the dossier in accordance with point b clause 2 Article 30 of Decree No. 98/2021/N■-CP.

After 90 days from the date of the C■c HT&TBYT's notification of request, if the organization/individual does not supplement or amend the dossier, or if after 05 amendments/supplementations to the dossier from the date of the first request for amendment/supplementation by the C■c HT&TBYT the dossier still does not satisfy the requirements, the procedure for requesting issuance of the circulation number must be restarted from the beginning.

6.2.3. For dossiers under the fast-track issuance case:

a) Where there is no request for amendment or supplementation of the dossier, the C■c HT&TBYT has the responsibility to: organize appraisal for issuance of the circulation number within 10 working days from the date of receipt of a complete and valid dossier (including documents confirming payment of the appraisal fee for issuance of the circulation license as prescribed by the Ministry of Finance). In cases where the circulation number is not granted, a written response stating the reason must be issued.

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b) Where the dossier is incomplete, the C■c HT&TBYT must notify the organization requesting issuance of the circulation number to supplement and amend the dossier, clearly stating which documents must be supplemented and which contents must be amended, within 10 working days from the date of receipt of a complete and valid dossier.

©) Upon receipt of the request for amendment and supplementation of the dossier, the organization/individual must amend and supplement in accordance with the notified contents and send it to the C■c HT&TBYT.

Where the organization/individual has amended and supplemented the dossier but not in accordance with the request, the C■c HT&TBYT shall notify the organization/individual to continue completing the dossier in accordance with point b clause 3 Article 30 of Decree No. 98/2021/N■-CP.

After 90 days from the date of the C■c HT&TBYT's notification of request, if the organization/individual does not amend or supplement the dossier, or if after 03 amendments/supplementations to the dossier from the date of the first request for amendment/supplementation by the C■c HT&TBYT the dossier still does not satisfy the requirements, the procedure for requesting issuance of the circulation number must be restarted from the beginning.

6.2.4. For dossiers under the emergency issuance case:

a) Where there is no request for amendment or supplementation of the dossier, the C■c HT&TBYT has the responsibility to: organize appraisal for issuance of the circulation number within 10 working days from the date of receipt of a complete and valid dossier (including documents confirming payment of the appraisal fee for issuance of the circulation license as prescribed by the Ministry of Finance). In cases where the circulation number is not granted, a written response stating the reason must be issued.

The C■c HT&TBYT only appraises the legal documents specified at points b, c, d, ■ and e clause 4 Article 30 of Decree No. 98/2021/N■-CP. For the remaining contents, the organization/individual shall be responsible for the accuracy and legality of these documents; the C■c HT&TBYT shall conduct post-market inspection of these contents after issuance of the circulation number.

b) Where the dossier is incomplete, the C■c HT&TBYT must notify the organization/individual to supplement and amend the dossier, clearly stating which documents must be supplemented and which contents must be amended, within 08 working days from the date of receipt of a complete and valid dossier.

c) Upon receipt of the request for dossier supplementation and amendment, the organization/individual must supplement and amend in accordance with the notified contents and send it to the C■c HT&TBYT.

Where the organization/individual has supplemented and amended the dossier but not in accordance with the request, the C■c HT&TBYT shall notify the organization/individual to continue completing the dossier in accordance with point b clause 4 Article 30 of Decree No. 98/2021/N■-CP.

After 90 days from the date of the C■c HT&TBYT's notification of request, if the organization/individual does not supplement or amend the dossier, the procedure for requesting issuance of the circulation number must be restarted from the beginning.

6.2.5. For other medical device dossiers: L

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a) Where there is no request for amendment or supplementation of the dossier, the C■c HT&TBYT has the responsibility to: organize appraisal for issuance of the circulation number within 45 days from the date of receipt of a complete and valid dossier (including documents confirming payment of the appraisal fee for issuance of the circulation license as prescribed by the Ministry of Finance). In cases where the circulation number is not granted, a written response stating the reason must be issued.

b) Where the dossier is incomplete, the C[■]c HT&TBYT must notify the organization/individual to supplement and amend the dossier, clearly stating which documents must be supplemented and which contents must be amended, within 40 days from the date of receipt of a complete and valid dossier.

c) Upon receipt of the request for dossier supplementation and amendment, the organization/individual must supplement and amend in accordance with the notified contents and send it to the C[■]c HT&TBYT.

Where the organization/individual has supplemented and amended the dossier but not in accordance with the request, the C[■]c HT&TBYT shall notify the organization/individual to continue completing the dossier in accordance with point b clause 5 Article 30 of Decree No. 98/2021/N[■]-CP.

After 90 days from the date of the C[■]c HT&TBYT's notification of request, if the organization/individual does not supplement or amend the dossier, or if after 03 amendments/supplementations to the dossier from the date of the first request for amendment/supplementation by the C[■]c HT&TBYT the dossier still does not satisfy the requirements, the procedure for requesting issuance of the circulation number must be restarted from the beginning.

6.2.6. Within 01 working day from the date of issuance of the circulation number, the C[■]c HT&TBYT has the responsibility to publicly disclose on the electronic information portal for medical device management the following information:

a) Name, classification, manufacturing establishment, country of manufacture of the medical device;

b) Circulation number of the medical device;

c) Name and address of the medical device owner;

d) Name and address of the circulation number owner;

■) Name and address of the medical device warranty service establishment;

e) Documents in the circulation registration dossier of the medical device, except for the documents specified at point e clause 1 and point c clause 5 Article 30 of Decree No. 98/2021/N[■]-CP.

g) Intended use of the medical device.

6.3. Place of receipt and return of results

Receipt and return of results online on the electronic information portal for medical device management.

6.4. Fees

6.4.1. Circular No. 59/2023/TT-BTC dated 30/8/2023 of the Minister of Finance regulating rates, collection, remittance, management and use of fees in the health sector:

- Appraisal for new issuance for Class C, D medical devices: 6.000.000 VND/01 dossier.

6.4.2. Circular No. 64/2025/TT-BTC dated 30 June 2025 of the Minister of Finance regulating fee and charge rates and exemptions of certain fees and charges to support enterprises and citizens:

- Appraisal for new issuance for Class C, D medical devices: 3.000.000 VND/01 dossier.

6.4.3. Where the documents cited in this procedure are amended, supplemented or replaced, implementation shall comply with the newly amended, supplemented or replaced documents.

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| No. | Code | Form name |

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| ĩ | BM01/BYT-TTB | List of dossiers requesting new issuance of circulation numbers submitted to the Council |

| 2 | BM02/BYT-TTB | List of dossiers requesting new issuance of circulation numbers after the Council meeting |

8. Record retention

- Dossier set of the organization/individual (stored on the System).
- Expert appraisal opinions (stored on the System).
- Notice of dossier supplementation (if any)
- Summary table of review results
- Dossier summary sheet submitted to the Appraisal Council.
- Minutes of the Appraisal Council meeting.
- Submission sheet to the Leadership of the Council HT&TBYT for issuance of the certificate,
- Medical device circulation registration certificate.
- Notice of ineligibility for issuance of the medical device circulation registration certificate (for dossiers not granted).
- Decision on withdrawal of the circulation number (for dossiers having the circulation number withdrawn).

9. Forms:

9.1. BM01/BYT-TTB

List of dossiers requesting new issuance of circulation numbers submitted to the Council

| No. | Dossier information | Product owner | Medical device type/name | Medical device code |
Manufacturer/manufacturing country | Validity of dossier documents | Handling opinion | Remarks |

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9.2. BM02/BYT-TTB

List of dossiers requesting new issuance of circulation numbers after the Council meeting

| No. | Dossier information | Product owner | Medical device type/name | Medical device code |
Manufacturer/manufacturing country | Validity of dossier documents | Handling opinion | Council opinion |

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