

**MINISTRY OF HEALTH OF  
VIETNAM**

**THE SOCIALIST REPUBLIC OF VIETNAM  
Independence- Freedom- Happiness**

No. 8329/BYT-HTTP

Ha Noi, 30 December, 2023

V/v inspecting and reviewing the  
procedures for declaring medical devices

**To:** The Department of Health, centrally governed city  
(Hereinafter referred to as The Department of Health)

On April 12, 2023, the Ministry of Health issued Dispatch No. 2098/BYT-TB-CT, sent to the Department of Health, requesting a review and inspection of procedures related to the declaration of medical devices. This includes the declaration procedure of eligibility for manufacturing medical device, the declaration procedure of eligibility for trading class BCD medical device and the standard declaration for class A, B medical device on the online public service system for managing medical device at <https://dmec.moh.gov.vn> (hereinafter referred to as the System <https://dmec.moh.gov.vn>), in accordance with the regulations in the documents governing medical device (Attached to Dispatch No. 2098/BYT-TB-CT).

However, the Ministry of Health has received several informations related to lowering the risk level of medical device of the production and import facilities to classify the product as medical device class A or B and the implementation of standards declaration for medical device of class A or B is not in accordance with the regulations at the Department of Health. In order to ensure that the procedures for declaring medical device on the System <https://dmec.moh.gov.vn> fall within the scope of resolution by the Department of Health in compliance with regulations and to promptly rectify and address any violations (if any); the Ministry of Health urgently requests the Department of Health to carry out the followings:

1. Issuing documents requested the production, purchase, and import/export facilities of medical device within the jurisdiction to:

- Conduct a thorough review of the declarations profiles of medical device on the System <https://dmec.moh.gov.vn>, in accordance with the provisions of Decree No. 36/2016/ND-CP dated May 15, 2016, and Decree No. 98/2021/ND-CP dated November 8, 2021, issued by the Government regarding prescribing medical device management and related documents including Emphasize the review of the results of classifying medical device to ensure compliance with regulations on the classification of medical device.

- Verify the legality and accuracy of the submitted documents and ensure that the documents in the dossier remain valid throughout the implementation process. Take responsibility for retaining the documents in accordance with the regulations in Decree No. 07/2023/ND-CP dated March 3, 2023, Amendments to government's Decree no. 98/2021/ND-CP dated november 08, 2021 prescribing medical device management

2. Urgently organize inspections, audits, and post-audits regarding the implementation of procedures for declaring standards applicable to medical device of class A and B. Execute the revocation of declaration numbers as per the regulations stipulated in Decree No. 36/2016/ND-CP, Decree No. 98/2021/ND-CP by the Government on prescribing medical device management, and Decree No. 07/2023/ND-CP dated March 3, 2023, amendments to government's Decree no. 98/2021/ND-CP dated November 08, 2021 prescribing medical

device management, including provisions on the classification of medical devices and related documents.

3. Report to the Ministry of Health (through the Department of Infrastructure and Medical Device):

- Provide the results of the review and inspection concerning cases where the procedures for declaring medical devices at the Department of Health do not comply with the regulations, as requested in Dispatch No. 2098/BYT-TB-CT dated April 12, 2023, from the Ministry of Health.
- Inform the leadership and specialists at the Department of Health responsible for the procedures for declaring medical devices, including the following details: Full name, telephone number, email address) before January 15, 2024.

**PP. MINISTER  
DEPUTY MINISTER**

**Do Xuan Tuyen**

