

LEGAL UPDATE (November 22nd, 2021)

In this issue, we would like to bring to your attention to the following:

- The Decree No. 97/2021/ND-CP amending, supplementing certain provisions of the Decree No. 23/2018/ND-CP on compulsory fire and explosion insurance.
- The Decree No. 98/2021/ND-CP on medical devices management.

1. The Decree No. 97/2021/ND-CP amending, supplementing certain provisions of the Decree No. 23/2018/ND-CP on compulsory fire and explosion insurance

On November 8th, 2021, the Government has promulgated the Decree No. 97/2021/ND-CP amending, supplementing certain provisions of the Decree No. 23/2018/ND-CP on compulsory fire and explosion insurance (hereinafter referred to as “**Decree No. 97/2021**”) with a few noteworthy points as follows:

a. Supplement the regulation on the obligation of agencies, organizations and individuals who have the establishment being a risk of fire and explosion

Decree No. 97/2021/ND-CP supplements a provision on the obligation of agencies, organizations and individuals who have the establishment being a risk of fire and explosion in Article 15b. Accordingly, such agencies, organizations and individuals are obligated to identify the A, B, C, D, E levels of risk of fire and explosion of their industrial production establishments as regards establishments being a risk of fire and explosion in accordance with the laws on fire prevention and extinguishment.

In addition, Decree No. 97/2021/ND-CP also supplements the regulation on the Ministry of Public Security’s responsibility for recording the risk of fire and explosion level. In particular, the Ministry of Public Security will rely on the determination of fire and explosion risk level of agencies, organizations and individuals who have the establishment being a risk of fire and explosion to record the risk level of industrial establishments having A, B, C, D, E risk levels in the Minutes of acceptance or the Minutes of safety inspection on fire prevention and extinguishment.

b. Certificates of compulsory fire and explosion insurance

When Decree No. 97/2021/ND-CP takes effect, all non-life insurance enterprises and branches of foreign non-life insurance enterprises in Vietnam (hereinafter referred to as “**insurance enterprises**”) will have to issue Compulsory fire and explosion insurance certificates to their policyholders. These Compulsory fire and explosion insurance

certificates shall be designed according to the insurance enterprises and shall include the following contents:

- Name, address of the insurance enterprise, policyholder, insured person;
- Establishment directory (specify which fire and explosion risk establishment directory do the establishment belong to in accordance with the laws on fire prevention and extinguishment);
- Address of the insured property;
- The insured property;
- The insured amount;
- Insurance deduction rate;
- Term of insurance;
- Insurance fee ratio, insurance fee;
- Name, address, hotline number of the insurance enterprise;
- Date of issuance of the Insurance certificate.

In case the Insurance certificate is issued in digital form, the insurance enterprise shall comply with the regulations of the Law on E-transactions and its guidance documents. The digital Insurance certificates shall fully comply with current regulations and sufficiently reflect the aforementioned contents.

Decree No. 97/2021/ND-CP will take effect from December 23rd, 2021.

2. The Decree No. 98/2021/ND-CP on medical devices management

On the last November 8th, 2021, the Government has promulgated the Decree No. 98/2021/ND-CP on medical devices management (hereinafter referred to as “**Decree No. 98/2021/ND-CP**”) to replace the former Decree No. 36/2016/ND-CP and create a firmer legal corridor in the classification, production, trade, export, import, management and use of medical devices at medical facilities. Some noteworthy points of this Decree can be briefed as follows:

a. **Type-B medical devices: Changing from circulation registration to declaration of applied standards**

According to new regulations, before circulating type-B medical devices in the market, organizations that are the owners of such medical devices, organizations authorized by the owners of such medical devices or other relevant organizations shall proceed with the declaration of applied standards instead of registering the circulation as before. The

circulation registration files already submitted for type-B will be transformed into the declaration of applied standards without having to re-submit the examination fee for circulation permits.

b. Extending the term of import permits for medical devices until the end of 31/12/2022

Decree No. 98/2021 also extends the value of import permits issued before 01/01/2022 with regard to certain medical devices items until the end of 31/12/2022 as follows:

- Import permits of medical devices that are not in vitro diagnostic reagents permitted for import from January 01st, 2018 shall be effective until the end of December 31st, 2022 and shall not be setted limit on import volume;
- Medical devices which are not subject to import permits (except for chemicals, insecticidal, germicidal preparations used for domestic appliances and medical sectors with the sole purpose of sterilizing medical devices) and have been classified as type-C, type-D medical devices announced by the Ministry of Health on its digital information portal shall continue to be allowed for import until the end of 31/12/2022 in accordance with demands, without any limitations on import volume and without the need of Ministry's confirmation on being medical devices when performing customs clearance procedures.

Applications for the issuance of import permits for medical devices submitted before January 01st, 2022 shall continue to be processed according to regulatory documents promulgated by the Ministry of Health before the date of entry into force of Decree No. 98/2021. Import permits issued in accordance with this provision shall be effective until the end of December 31st, 2022.

c. Circulation numbers of medical devices will take effect from 01/01/2022

The date of entry into force of circulation numbers of medical devices was stipulated in Article 68 of Decree No. 36/2016/ND-CP on medical devices management and respectively amended, supplemented by Decree No. 169/2018/ND-CP and Decree No. 03/2020/ND-CP to be delayed from the original 01/01/2018 to 01/01/2020 and most recently 01/01/2022. At the moment, Decree No. 98/2021/ND-CP provides no regulation on further delay in this date so it can be construed that circulation numbers will commence their effect on 01/01/2022.

We hope this Monthly Newsletter would bring you useful information.

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