Annex 3
 to the Procedure

Ministry of Health of Ukraine
 Kyiv

REGISTRATION CERTIFICATE
 of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (medicinal product, medical immunobiological product, blood product)

№

The decision on state emergency registration in Ukraine of medicinal product/medical immunobiological product/blood product approved by the MoH Order of \_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_\_  №       .

According to the Decrees of President of Ukraine “On imposition of martial law in Ukraine” of February 24, 2022 № 64 and “On extension of the period of martial law in Ukraine” of March 14, 2022 № 133

medicinal product/medical immunobiological product/blood product \_\_\_\_\_\_\_\_\_\_\_\_

            (underline as appropriate)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(trade name)

has been registered in Ukraine for one year and/or for the period of martial law or for six months

after termination or cancellation of martial law for use by health care professionals in health care settings having a license to carry out economic activity in the health care sector, it may be purchased by business entities engaged in wholesale of medicinal products, dispensed and/or transferred by them to health care settings having a license to carry out economic activity in the health care sector, military administrations, units of the Armed Forces, legal entities, in particular those who volunteer and provide humanitarian and/or charity support without the right to further retail sale.

The validity period of registration certificate in Ukraine is for one year and/or for the period of martial law or for six months after termination or cancellation of martial law.

Medicinal product/medical immunobiological product/blood product has been registered subject to obligations:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Applicant and his location \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The registration certificate has been drawn up on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_\_.

INFORMATION

on medicinal product/medical immunobiological product/blood product Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Pharmaceutical form, strength \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Route of administration \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The Anatomical Therapeutic Chemical (ATC) code\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Indications \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Type, size and contents of package \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Shelf life \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Manufacturer(s) of medicinal product/medical immunobiological product/blood product \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

OPINION
 on qualitative and quantitative composition of medicinal product/medical immunobiological product/blood product

1. Name of medicinal product/medical immunobiological product/blood product, pharmaceutical form, strength \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Qualitative and quantitative composition of medicinal product/medical immunobiological product/blood product:

active substances \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 excipients \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (position of a person who signed the registration certificate) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (signature) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (full name) |