2023 -10- 04

CHIEF PHARMACEUTICAL INSPECTOR

**ISF.405.26.2023.IP.1**
**WTC/0637_01_01/194**

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

**Part 1**

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

**Chief Pharmaceutical Inspector**
/the Competent Authority of Poland/

confirms the following:

the importer

**SciencePharma spółka z ograniczoną odpowiedzialnością**

**ul. Chełmska 30/34, 00-725 Warszawa, POLAND**

site address

**SciencePharma spółka z ograniczoną odpowiedzialnością**

**ul. Chełmska 30/34, 00-725 Warszawa, POLAND**

has been inspected under the national inspection programme in connection with importation authorisation No. **271/0637/22** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2022, item 2301 as amended).

From the knowledge gained during inspection of this importer, the latest of which was conducted on **27-28/07/2023**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive (EU) 2017/1572.

This certificate reflects the status of the importation site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/).

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57

www.gif.gov.pl
gif@gif.gov.pl

**Part 2**

| |
|---|
| Importation of Human Medicinal Products |

| | |
|---|---|
| **2 IMPORTATION OF MEDICINAL PRODUCTS** | |
| **2.2** | **Batch certification of imported medicinal products** |
| | **2.2.1 Sterile Products**<br>2.2.1.1 Aseptically prepared<br>**2.2.3 Biological medicinal products**<br>2.2.3.6 Human or animal extracted products |

On the Chief Pharmaceutical Inspector authority

*Paweł Kułka*
Deputy Chief Pharmaceutical Inspector

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57

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gif@gif.gov.pl