2024 -01- 25

CHIEF PHARMACEUTICAL INSPECTOR

ISF.405.4.2024.IP.2
WTC/0393_03_01/7

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 94(1) of Regulation No 2019/6

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

PRESPACK Sp. z o.o.

ul. Grzybowa 8 lok. C, 62-081 Wysogotowo, POLAND

site address

PRESPACK Sp. z o.o.

ul. Grzybowa 8C, 62-081 Wysogotowo, POLAND

Has been inspected under the national inspection programme in connection with manufacturing *authorisation no.* **039/0393/15** *in accordance with* Art. 88 *of Regulation* (EU) No 2019/6, Art. 38 and Art. 51a point 2 Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2022, item 2301 as amended).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **04-05/12/2023**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 91/412/EEC.

This certificate reflects the status of the manufacturing 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 INSPEKTOR FARMACEUTYCZNY

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

Part 2

Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packing

Any restrictions or clarifying remarks related to the scope of this certificate:

Points 1.1.3 and 1.2.2 only in scope of certification of the repackaged finished product.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

Marcin Wójtowicz

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