Część 2

Produkty lecznicze przeznaczone dla ludzi

1 OPERACJE WYTWÓRCZE	
1.1	**Produkty sterylne**
	1.1.3 Certyfikacja serii
1.2	**Produkty niesterylne**
	1.2.2. Certyfikacja serii
1.5	**Pakowanie**
	1.5.2 Pakowanie w opakowania zewnętrzne

Zastrzeżenia lub uwagi wyjaśniające dotyczące zakresu certyfikatu:

Punkty 1.1.3 i 1.2.2 Certyfikacja serii tylko w zakresie punktu 1.5.2.

Certyfikat został wydany na podstawie inspekcji zdalnej.

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

data: 2020 -11- 30

Główny Inspektorat Farmaceutyczny
ul. Senatorska 12, 00-082 Warszawa, Polska
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Paweł Piotrowski
Główny Inspektor Farmaceutyczny

Chief Pharmaceutical Inspector

IWPS.405.6.2020.MB.1
WTC/0559_01_01/130

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

InPharm Sp. z o.o. Servieces Sp. k.
ul. Chełmżyńska 249, 04-458 Warszawa, POLAND

site address

InPharm Sp. z o.o. Servieces Sp. k.
ul. Chełmżyńska 249, 04-458 Warszawa, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. 236/0559/16 in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2020, item 944).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **13-14/10/2020**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC.

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.

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 EudraGMP. If it does not appear, please contact the issuing authority.

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

date: 2020 -11- 30

Chief Pharmaceutical Inspectorate
ul. Senatorska 12, 00-082 Warszawa, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Paweł Piotrowski
Chief Pharmaceutical Inspector

Part 2

Human 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 Batch certification only in scope of the point 1.5.2

The certificate was issued on the basis of remote inspection.

date: 2020 -11- 30

Chief Pharmaceutical Inspectorate
ul. Senatorska 12, 00-082 Warszawa, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Paweł Piotrowski
Chief Pharmaceutical Inspector