CERTIFICATE No. GIF-IW-400/0265_01_01/04/142/17

Chief Pharmaceutical Inspector

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

Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Bydgoszczy

ul. Ks. Markwarta 8, 85-015 Bydgoszcz, POLAND

site address

Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Bydgoszczy

ul. Ks. Markwarta 8, 85-015 Bydgoszcz, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **049/0265/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2016, item 2142).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **25-28/04/2017**, 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

acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

date: 2017 -06- 29

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

Zbigniew Niewójt
Chief Pharmaceutical Inspector

CERTIFICATE No. GIF-IW-400/0265_01_01/04/142/17

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.3	**Biological medicinal products**
	1.3.1 Biological medicinal products 1.3.1.1 Blood products **1.3.2 Batch certification** 1.3.2.1 Blood products
1.4	**Other products or processing activity**
	1.4.1.3 Other: human plasma for fractionation obtained from whole blood, human plasma for fractionation obtained by plasmapheresis, hyperimmune plasma
1.6	**Quality control testing**
	1.6.3 Chemical/Physical **1.6.4 Biological**

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

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ul. Ks. Markwarta 8, 85-015 Bydgoszcz, POLAND

site address

Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Bydgoszczy

Terenowy Oddział w Inowrocławiu

ul. Poznańska 97, 88-100 Inowrocław, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **049/0265/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2016, item 2142).

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.3	**Biological medicinal products**
	1.3.1 Biological medicinal products 1.3.1.1 Blood products
1.4	**Other products or processing activity**
	1.4.1 Manufacture of: 1.4.1.3 Other: human plasma for fractionation obtained by plasmapheresis, hyperimmune plasma
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

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the manufacturer

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ul. Ks. Markwarta 8, 85-015 Bydgoszcz, POLAND

site address

Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Bydgoszczy

Terenowy Oddział we Włocławku

ul. Lunewil 15, 87-800 Włocławek, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **049/0265/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2016, item 2142).

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1 MANUFACTURING OPERATIONS	
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	1.3.1 Biological medicinal products 1.3.1.1 Blood products
1.4	**Other products or processing activity**
	1.4.1 Manufacture of: 1.4.1.3 Other: human plasma for fractionation obtained by plasmapheresis, hyperimmune plasma
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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ul. Ks. Markwarta 8, 85-015 Bydgoszcz, POLAND

site address

Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Bydgoszczy

Terenowy Oddział w Brodnicy

ul. 18 Stycznia 36B, 87-300 Brodnica, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **049/0265/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2016, item 2142).

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site address

Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Bydgoszczy

Terenowy Oddział w Toruniu

ul. Św. Józefa 53-59, 87-100 Toruń, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **049/0265/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2016, item 2142).

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site address

Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Bydgoszczy

Terenowy Oddział w Grudziądzu

ul. Włodka 16-18, 86-300 Grudziądz, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **049/0265/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2016, item 2142).

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