

Chief Pharmaceutical Inspectorate

CERTIFICATE NUMBER: **ISF.405.142.2024.IP.3 WTC/0119_02_01/270**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1,2}

Part 1

Issued following an inspection in accordance with Art. 63 of Regulation (EU) 536/2014 as amended

The competent authority of Poland confirms the following:

The manufacturer: **Wytwornia Surowic I Szczepionek Biomed Sp. z o.o.**

Site address: **Chelmska 30/34, Warsaw, 00-725, Poland**

OMS Organisation Id. / OMS Location Id.: **ORG-100002621 / LOC-100004239**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **103/0119/15** in accordance with Art. 61 of Regulation (EU) No 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2024-09-20**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.³

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.

¹The certificate referred to in paragraph Art. 15 of Directive 2001/20/EC is also applicable to importers.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids
	<i>1.1.3 Batch certification</i>
1.5	Packaging
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.3 Chemical/Physical</i>

2024-11-15

Name and signature of the authorised person of the
Competent Authority of Poland

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Chief Pharmaceutical Inspectorate
Tel: *Confidential*
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Chief Pharmaceutical Inspectorate

CERTIFICATE NUMBER: **ISF.405.142.2024.IP.1 WTC/0119_02_01/268**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1,2}

Part 1

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

The competent authority of Poland confirms the following:

The manufacturer: **Wytwornia Surowic I Szczepionek Biomed Sp. z o.o.**

Site address: **Chelmska 30/34, Warsaw, 00-725, Poland**

OMS Organisation Id. / OMS Location Id.: **ORG-100002621 / LOC-100004239**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **103/0119/15** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2024-09-20**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572.³

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.

¹The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.12 Suppositories
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.2 Immunological products 1.3.1.6 Human or animal extracted products 1.3.1.8 Other: biologically active starting materials(en)
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.2 Immunological products 1.3.2.6 Human or animal extracted products
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.12 Suppositories
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

2024-11-15

Name and signature of the authorised person of the
Competent Authority of Poland

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Chief Pharmaceutical Inspectorate

CERTIFICATE NUMBER: **ISF.405.142.2024.IP.2 WTC/0119_02_01/269**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1,2}

Part 1

Issued following an inspection in accordance with Art. 94(1) of Regulation (EU) 2019/6 as amended

The competent authority of Poland confirms the following:

The manufacturer: **Wytwornia Surowic I Szczepionek Biomed Sp. z o.o.**

Site address: **Chelmska 30/34, Warsaw, 00-725, Poland**

OMS Organisation Id. / OMS Location Id.: **ORG-100002621 / LOC-100004239**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **103/0119/15** in accordance with Art. 88 of Regulation (EU) 2019/6.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2024-09-20**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC.³

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.

¹The certificate referred to in paragraph Art. 80(5) of Directive 2001/82/EC is also applicable to importers.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Veterinary Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids
	<i>1.1.3 Batch certification</i>
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.2 Immunological products 1.3.1.6 Human or animal extracted products 1.3.1.8 Other: biologically active starting materials(en)
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.2 Immunological products 1.3.2.6 Human or animal extracted products
1.5	Packaging
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

2024-11-15

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