

ISF.405.121.2024.IP.1
WTC/0432_01_01/217

2024-09-30

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 manufacturer and importer

SteriPack Medical Poland Sp. z o.o.**Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice, POLAND**

site address

SteriPack Medical Poland Sp. z o.o.**Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice, POLAND**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **026/0432/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2024, item 686).

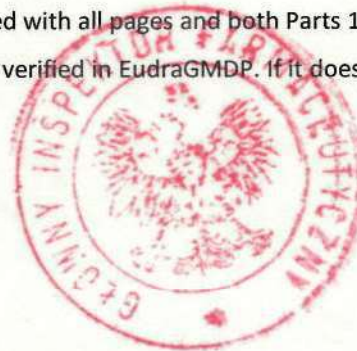
From the knowledge gained during inspection of this manufacturer and importer, the latest of which was conducted on **10/07/2024**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive (EU) 2017/1572.

This certificate reflects the status of the manufacturing and 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.



Chief Pharmaceutical Inspector

Łukasz Pietrzak

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	Sterile Products
	1.1.3 Batch certification
1.5	Packaging
	1.5.2 Secondary packing

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.3	Other importation activities
	2.3.2 Importation of intermediate which undergoes further processing: solution for injection in primary packing

2024-09-30



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Chief Pharmaceutical Inspector
Łukasz Pietrzak



2024-09-30

ISF.405.121.2024.IP.2
WTC/0432_01_01/218

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 63(4) of Regulation No 536/2014

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer and importer

SteriPack Medical Poland Sp. z o.o.**Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice, POLAND**

site address

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From the knowledge gained during inspection of this manufacturer and importer, the latest of which was conducted on **10/07/2024**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Commission Delegated Regulation (EU) 2017/1569.

This certificate reflects the status of the manufacturing and 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.

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Chief Pharmaceutical Inspector
Lukasz Pietrzak
Lukasz Pietrzak

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS	
1.1	Sterile products
	1.1.3 Batch certification
1.3	Biological medicinal products
	1.3.2.8 Other biological medicinal products: medicinal product in the form of solution for injection or lyophilisate for solution, containing chemically conjugated unfractionated heparin and human serum albumin
1.5	Packaging
	1.5.2 Secondary packing

2 IMPORTATION OF HUMAN INVESTIGATIONAL MEDICINAL PRODUCTS	
2.3	Other importation activities
	2.3.2 Importation of intermediate which undergoes further processing: lyophilisate for solution preparat in a primary packing, solution for injection

2024-09-30



Chief Pharmaceutical Inspector
Lukasz Pietrzak
Lukasz Pietrzak





ISF.405.18.2026.IP.2
WTC/0432_01_01/34

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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Chief Pharmaceutical Inspector

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Łęg, ul. Japońska 1 55-220 Jelcz-Laskowice, POLAND

site address

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Łęg, ul. Japońska 1 55-220 Jelcz-Laskowice, POLAND

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From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **16/12/2025 – 18/12/2025**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Commission Delegated Regulation (EU) 2017/1569.

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.

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2026 -02- 2 6



Chief Pharmaceutical Inspector

Łukasz Pietrzak

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.6 Quality control testing

1.6.3 Chemical/Physical

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

Point 1.6.3 applies to the functional tests of autoinjectors (AI) and pre-filled syringes (PFS)

2026 -02- 2 6



Chief Pharmaceutical Inspector

Łukasz Pietrzak



ISF.405.18.2026.IP.1
WTC/0432_01_01/33

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER¹

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Chief Pharmaceutical Inspector

Łukasz Piętrzak

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.6 Quality control testing

1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

Point 1.6.3 applies to the integrity testing of the finished product packaging and functional tests of autoinjectors (AI).

2026 -02- 2 6



Chief Pharmaceutical Inspector

Łukasz Pietrzak

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 94(1) of Regulation (EU) 2019/6 is also applicable to importers.



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2026 -02- 2 6



Chief Pharmaceutical Inspector

Łukasz Pietrzak

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.6 Quality control testing

1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

Point 1.6.3 applies to the integrity testing of the finished product packaging and functional tests of autoinjectors (AI).

2026 -02- 2 6



Chief Pharmaceutical Inspector

Łukasz Pietrzak

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 94(1) of Regulation (EU) 2019/6 is also applicable to importers.