Chief Pharmaceutical Inspector

IWPS.405.10.2020.SM.1
WTC/0119_02_01/153

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

Wytwórnia Surowic i Szczepionek BIOMED Sp. z o.o.

ul. Chełmska 30/34, 00-725 Warszawa, POLAND

site address

Wytwórnia Surowic i Szczepionek BIOMED Sp. z o.o.

ul. Chełmska 30/34, 00-725 Warszawa, POLAND

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 transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2020, item 944, as amended).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **14-18/09/2020**, 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.

INSPEKTOR FARMACEUTYCZNY

date: 09.12.2020

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**
	1.1.1 Aseptically prepared 1.1.1.4 Small volume liquids **1.1.2 Terminally sterilised** 1.1.2.3 Small volume liquids **1.1.3 Batch certification**
1.3	**Biological medicinal products**
	1.3.1 Biological medicinal products 1.3.1.2 Immunological products 1.3.1.6 Human or animal extracted products 1.3.1.8 Other biological medicinal products: biologically active starting materials) **1.3.2 Batch certification** 1.3.2.2 Immunological products 1.3.2.6 Human or animal extracted products
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility **1.6.2 Microbiological: non sterility** **1.6.3 Chemical/Physical** **1.6.4 Biological**

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

The certificate was issued on the basis of a remote inspection.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 09.12.2020

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