

CERTIFICATE No. GIF-IW-400/0120_01_01/04/197/14

*Main 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

Main Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer

**„BIOMED-LUBLIN” Wytwórnia Surowic i Szczepionek
Spółka Akcyjna
10 Uniwersytecka Str., 20-029 Lublin, POLAND**

site address

**„BIOMED-LUBLIN” Wytwórnia Surowic i Szczepionek
Spółka Akcyjna
10 Uniwersytecka Str., 20-029 Lublin, POLAND**

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **GIF-IW-400/0120/01/696/ZW278/14** in accordance with Art. 40 of Directive 2001/83/EC transposed in pharmaceutical law of 6th of September 2001 (Dz. U. z 2008 r. Nr 45, poz. 271, z późn. zm.).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **04-07/11/2014**, 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, after which time the issuing authority should be consulted.

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.



date: 2015 -02- 03

Main Pharmaceutical Inspectorate
12 Senatorska Str., 00-082 Warsaw, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Zofia Ulz
Main Pharmaceutical Inspector

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Part 2

Human Medicinal Products

| | |
|-----------------------------------|---|
| 1 MANUFACTURING OPERATIONS | |
| 1.1 | Sterile Products |
| | <p>1.1.1 Aseptically prepared</p> <p>1.1.1.2 Lyophilisates</p> <p>1.1.2 Terminally sterilised</p> <p>1.1.2.3 Small volume liquids</p> <p>1.1.3 Batch certification only</p> |
| 1.3 | Biological medicinal products |
| | <p>1.3.1 Biological medicinal products</p> <p>1.3.1.2 Immunological products: lyophilisates</p> <p>1.3.2 Batch certification only</p> <p>1.3.2.1 Blood products</p> <p>1.3.2.2 Immunological products</p> <p>1.3.2.6 Human or animal extracted products</p> |
| 1.4 | Other products or manufacturing activity (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), herbal or homeopathic products, bulk or total manufacturing, etc) |
| | <p>1.4.1 Manufacture of:</p> <p>1.4.1.3 Biological active starting materials</p> |
| 1.5 | Packaging only |
| | 1.5.2 Secondary packing |

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