CERTIFICATE No. GIF-IW-N-4022/55/11

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-N-4001/WTC120/21/11** 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 **12-14/04/2011**, 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 with the issuing authority.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 2011 -06- 06

Main Pharmaceutical Inspectorate
38/40, Długa Str., 00-238 Warsaw, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Zofia Ulz
Main Pharmaceutical Inspector

CERTIFICATE No. GIF-IW-N-4022/55/11

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS **Purchase of starting materials** **Control operations regarding supervision of production processes** **Batch Release** **Storage** **Distribution**	
1.2	**Non-sterile products**
	***1.2.1 Non-sterile products** (list of dosage forms)* 1.2.1.8 Other solid dosage forms
1.3	**Biological medicinal products**
	1.3.1 Biological medicinal products 1.3.1.7 Other biological medicinal products: lyophilisates
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)***
	1.4.1 Manufacture of: 1.4.1.3 Biological active starting materials
1.5	**Packaging only**
	1.5.2 Secondary packing

Any restriction related to the scope of this certificate:

The scope of certificate concerns manufacturing process conducted in Department of Lakcid, Department of Supporting Production, Department of Packing.

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

date: 2011 -06- 06

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Zofia Ulz
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