CERTIFICATE No. GIF-IW-400/0332_01_01/04/49/17

Chief Pharmaceutical Inspector

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 15 of Directive 2001/20/EC as amended

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

BioContract Sp. z o.o.

ul. Zambrowska 36, 61-051 Poznań, POLAND

site address

BioContract Sp. z o.o.

ul. Wojska Polskiego 48, 60-627 Poznań, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **101/0332/15** in accordance with Art. 13 of Directive 2001/20/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2008, No. 45, item 271 with amendments).

From the knowledge gained during inspection of this manufacturer the latest of which was conducted on **15-17/11/2016**, 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.

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

date: 2017 -02- 10

Chief Pharmaceutical Inspectorate
ul. Senatorska 12, 00-082 Warszawa, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Zbigniew Niewójt
Chief Pharmaceutical Inspector

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Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared 1.1.1.4 Small volume liquids **1.1.3 Batch certification**
1.3	**Biological medicinal products**
	1.3.1 Biological medicinal products 1.3.1.3 Cell therapy products **1.3.2 Batch certification** 1.3.2.3 Cell therapy products
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.3 Chemical/Physical **1.6.4 Biological**

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

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