



Chief Pharmaceutical Inspector

IWPS.405.93.2019.ABU.1

WTC/0348\_01\_01/219

## 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

**Narodowe Centrum Badań Jądrowych**

**ul. Andrzeja Sołtana 7, 05-400 Otwock, POLAND**

site address

**Narodowe Centrum Badań Jądrowych**

**ul. Andrzeja Sołtana 7, 05-400 Otwock, POLAND**

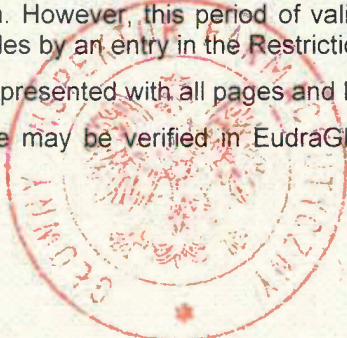
has been inspected under the national inspection programme in connection with manufacturing authorisation No. **195/0348/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6<sup>th</sup> of September 2001 (Journal of Laws from 2019, item 499).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **25-27/06/2019**, 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.

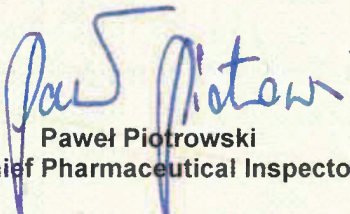
This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.



date: **2019 -09- 2 5**

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

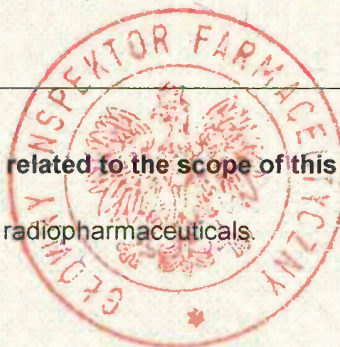
## Part 2

Human Medicinal Products

<b>1 MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile Products</b>
	<b>1.1.1 Aseptically prepared</b> 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids  <b>1.1.2 Terminally sterilised</b> 1.1.2.5 Other terminally sterilised prepared products: radionuclide generators  <b>1.1.3 Batch certification</b>
<b>1.5</b>	<b>Packaging</b>
	<b>1.5.2 Secondary packing</b>
<b>1.6</b>	<b>Quality control testing</b>
	<b>1.6.1 Microbiological: sterility</b> <b>1.6.2. Microbiological: non-sterility</b> <b>1.6.3 Chemical/Physical</b> <b>1.6.4 Biological</b>

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

Point 1.1.2.5 concerns manufacturing of radiopharmaceuticals.



date: 2019 -09- 25

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*Paweł Piotrowski*  
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