**ISF.405.89.2025.IP.2**
**WTC/0012_01_01/190**

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER[1]

**Part 1**

Issued following an inspection in accordance with Art. 94(1) of Regulation (EU) 2019/6

**Chief Pharmaceutical Inspector**

/the Competent Authority of Poland/

confirms the following:

the manufacturer

**Instytut Chemii i Techniki Jądrowej**

**ul. Dorodna 16, 03-195 Warszawa, POLAND**

site address

**Instytut Chemii i Techniki Jądrowej**

**ul. Dorodna 16, 03-195 Warszawa, POLAND**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **014/0012/15** in accordance with Art. 88 of Regulation (EU) 2019/6 Art. 38 and Art. 51a point 2 Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2025, item 750 as amended).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **03/06/2025 – 05/06/2025**, it is considered that it complies with the Good Manufacturing Practice laid down in Directive 91/412/EEC.

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.

Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu /

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 EudraGMDP. If it does not appear, please contact the issuing authority.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

2025 -08- 12

Chief Pharmaceutical Inspector

Łukasz Pietrzak

12 Senatorska str, 00-082 Warsaw, POLAND
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## Part 2

| Human Medicinal Products |
|---|

| 1 MANUFACTURING OPERATIONS | |
|---|---|
| **1.4** | **Other products or processing activity** |
| | **1.4.2 Sterilisation of active substances/excipients/finished product:**<br>1.4.2.6 Electron beam |

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

2025 -08- 12

Chief Pharmaceutical Inspector

Łukasz Pietrzak

[1] The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 94(1) of Regulation (EU) 2019/6 is also applicable to importers.

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