2024 -10- 01

CHIEF PHARMACEUTICAL INSPECTOR

ISF.405.122.2024.IP.2
WTC/0594_01_01/220

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

NYSK Holdings LLCOP

112 Str. no.217, Kjojlija, Municipality Petrovec, 1000 Skopje, NORTH MACEDONIA

site address

NYSK Holdings LLCOP

112 Str. no.217, Kjojlija, Municipality Petrovec, 1000 Skopje, NORTH MACEDONIA

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: Pharmaceutical Law of 6th of September 2001 ((Journal of Laws from 2024, item 686).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **09/08/2024**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Article 47 of Directive 2001/83/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.

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

Chief Pharmaceutical Inspector

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