Certificate No: **GMP 26/9**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with the requirements of Good Manufacturing Practice, of the Israeli laws and regulations (Pharmacist Regulations [Good Manufacturing Practice for Medicinal Products]2008)

and

Issued under the provisions of the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel

The competent authority of Israel confirms the following:

The manufacturer **Oxygen & Argon Works Ltd.**

Site address **1 Maoritsyo Levi St., Ramat Gavriel Ind. Zone, Migdal HaEmek, Israel**

Has been inspected under the Israeli inspection programme, in connection with manufacturing authorization no. **MIA 26**, in accordance with the above mentioned laws and regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **10 February 2022** (*last day of a distant assessment, see clarifying remarks section*), it is considered that it complies with the Good Manufacturing Practice requirements referred to in the ConformityAssessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel, and the above mentioned Israeli laws and regulations (*).

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.

(*) these requirements fulfill the GMP recommendations of WHO

MINISTRY OF HEALTH JERUSALEM
GOV. INSTITUTE FOR CONTROL AND STANDARD OF PHARMACEUTICALS
משרד הבריאות
13-07-2022

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Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS

1.2 Non-sterile products

1.2.1 Non-sterile products

1.2.1.7 Medicinal gases : *Oxygen , Nitrogen (as liquids)*

1.2.2 Batch certification

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

The manufacturer produces Medicinal Oxygen & Medicinal Nitrogen (as Liquids), and fills them in road tanks.

Due to the COVID-19 pandemic, last inspection was conducted as a distant assessment.

Name and signature of the authorized person of the Competent Authority of Israel:

Michael carmi, Pharmacist - GMP Inspector

Email: michael,carmi@moh.gov.il
Phone: office 972 -2-6551795, cell 972-50-6242452

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