Chief Pharmaceutical Inspector

IWPS.405.26.2019.KK.1.1
WTC/0061_01_01/48

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

Air Products Sp. z o.o.

ul. Komitetu Obrony Robotników 48, 02-146 Warszawa, POLAND

site address

Air Products Sp. z o.o.

ul. Bukowiecka 71, 03-893 Warszawa, POLAND

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **075/0061/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2017, item 2211).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **18-19/12/2018**, 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

date: 2020 -01- 31

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

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.7 Medicinal gases **1.2.2 Batch certification**
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.7 Medicinal gases
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 2020 -01- 31

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