MANUFACTURER'S AUTHORISATION [1] , [2]

1. Authorisation Number	DE_NW_01_MIA_2021_0021
2. Name of authorisation holder	Air Products GmbH
3. Address(es) of manufacturing site(s)	Air Products GmbH (ORG-100001810 / LOC-100009837), An der Kost 3, Hattingen, Nordrhein-Westfalen, 45527, Germany
4. Legally registered address of authorisation holder	An der Kost 3, Hattingen, Nordrhein-Westfalen, 45527, Germany
5. Scope of authorisation and dosage forms[2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 40 of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2021-12-10
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3(Addresses of Contract Manufacturing Site(s)) Annex 4(Addresses of Contract laboratories) Annex 5(Name of Qualified Person) Annex 6(Name of responsible persons) Annex 7(Date of inspection on which authorisation granted, scope of last inspection) Annex 8(Manufactured/ imported products authorised)[3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Air Products GmbH, An der Kost 3, Hattingen, Nordrhein-Westfalen, 45527, Germany

Additional Details:

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS(according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.7 Medicinal gases
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

1.2.1.7: - GOX medical in accordance with the Ph.Eur. specification Oxygenium, amongst others to produce in accordance with Air Products marketing authorisation No. 69557.00.00 - LOX medical in accordance with the Ph.Eur. specification Oxygenium, amongst others to produce in accordance with Air Products marketing authorisation No. 73062.00.00 - Filling of LOX medical in containers in accordance with SECT. 16 Abs. 3 AMWHV. 5.2: Replacement of transport damaged medical labels on third party manufactured cylinders by identical labels upon goods receipt.