Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

UK MIA 6183

AIR PRODUCTS PLC

AIR PRODUCTS PLC, MANCHESTER ROAD, CARRINGTON, MANCHESTER, M31 4TG, UNITED KINGDOM

AIR PRODUCTS PLC, HAWKSWORTH, HARRIER PARK, DIDCOT, OX11 7PL, UNITED KINGDOM

AIR PRODUCTS PLC, SALTEND LANE, HEDON, HULL,

HU12 8PP, UNITED KINGDOM

AIR PRODUCTS PLC, SHARP STREET, WALKDEN, WORSLEY, MANCHESTER, M28 3WA, UNITED KINGDOM

AIR PRODUCTS PLC, 2 MILLENNIUM GATE, WESTMERE DRIVE, CREWE, CW1 6AP, UNITED KINGDOM

AIR PRODUCTS PLC, 2 MILLENNIUM GATE, WESTMERE DRIVE, CREWE, CHESHIRE, CW1 6AP, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

01/03/2021

Annex 1 and/or Annex 2

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

8: Authorisation Date

9: Annexes attached

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AIR PRODUCTS PLC, MANCHESTER ROAD, CARRINGTON, MANCHESTER, M31 4TG, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Issue Date: 01 Mar 2021

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

[1.5.1] Primary packaging

[1.5.1.7] Medicinal gases

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AIR PRODUCTS PLC, HAWKSWORTH, HARRIER PARK, DIDCOT, OX11 7PL, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

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SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AIR PRODUCTS PLC, SALTEND LANE, HEDON, HULL, HU12 8PP, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

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Issue Date: 01 Mar 2021

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[1.5.1.7] Medicinal gases

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AIR PRODUCTS PLC, SHARP STREET, WALKDEN, WORSLEY, MANCHESTER, M28 3WA, UNITED KINGDOM

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

[1.5.1] Primary packaging

[1.5.1.7] Medicinal gases

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AIR PRODUCTS PLC, 2 MILLENNIUM GATE, WESTMERE DRIVE, CREWE, CW1 6AP, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Issue Date: 01 Mar 2021

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

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.7] Medicinal gases

[1.6] Quality control testing

[1.6.3] Chemical/Physical

