

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 15929

2: Name of authorisation holder AIR LIQUIDE LIMITED

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

AIR LIQUIDE - WOLVERHAMPTON, ENTERPRISE DRIVE, FOUR ASHES, WOLVERHAMPTON, WV10 7DF, UNITED KINGDOM

AIR LIQUIDE - WOLVERHAMPTON, GAILEY PARK, GRAVELLY WAY, STANDEFORD, WOLVERHAMPTON, WV10 7GW, UNITED KINGDOM

AIR LIQUIDE - COLESHILL, STATION ROAD, COLESHILL, BIRMINGHAM, B46 1JY, UNITED KINGDOM

AIR LIQUIDE - IRLAM, SORBY ROAD, NORTH BANK INDUSTRIAL PARK, IRLAM, MANCHESTER, M44 5BA, UNITED KINGDOM

4: Legally registered address of authorisation holder AIR LIQUIDE LIMITED, STATION ROAD, COLESHILL, BIRMINGHAM, B46 1JY, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

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

8: Authorisation Date 15/02/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AIR LIQUIDE - WOLVERHAMPTON, ENTERPRISE DRIVE, FOUR ASHES, WOLVERHAMPTON, WV10 7DF, 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 LIQUIDE - WOLVERHAMPTON, GAILEY PARK, GRAVELLY WAY, STANDEFORD, WOLVERHAMPTON, WV10 7GW, 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 LIQUIDE - COLESHILL, STATION ROAD, COLESHILL, BIRMINGHAM, B46 1JY, 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

[1.2.2] 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

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AIR LIQUIDE - IRLAM, SORBY ROAD, NORTH BANK INDUSTRIAL PARK, IRLAM, MANCHESTER, M44 5BA, 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