

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

UK MIA 735

2: Name of authorisation holder

BOC LIMITED

BOC BELFAST, PRINCE REGENT ROAD, CASTLEREAGH,
BELFAST, BT5 6RW, UNITED KINGDOM

BOC BRISTOL, WHITBY ROAD, BRISTOL, BS4 3QH, UNITED
KINGDOM

BOC WEMBLEY, EAST LANE, WEMBLEY, HA9 7PT, UNITED
KINGDOM

BOC MARGAM, LONGLANDS LANE, MARGAM, PORT TALBOT,
SA13 2NS, UNITED KINGDOM

BOC BRINSWORTH, BAWTRY ROAD, BRINSWORTH,
ROTHERHAM, S60 5NT, UNITED KINGDOM

BOC WORSLEY, PRIESTLEY ROAD, WORSLEY,
MANCHESTER, M28 2LX, UNITED KINGDOM

BOC FAWLEY, CHARLESTON ROAD, HARDLEY, HYTHE,
SOUTHAMPTON, SO45 3NX, UNITED KINGDOM

BOC COVENTRY, TERRY ROAD, COVENTRY, CV1 2BE,
UNITED KINGDOM

BOC PLYMOUTH, MAXWELL ROAD, PRINCE ROCK,
PLYMOUTH, PL4 0RT, UNITED KINGDOM

BOC WOLVERHAMPTON, LOWER WALSALL STREET,
WOLVERHAMPTON, WV1 2EP, UNITED KINGDOM

BOC MOTHERWELL, CHAPELKNOWE ROAD, CARFIN,
MOTHERWELL, ML1 5LF, UNITED KINGDOM

BOC LIMITED - HARLOW, UNIT D, RIVER WAY, HARLOW,
CM20 2DP, UNITED KINGDOM

BOC TOTTON, 7/8 BRUNEL ROAD, WESTWOOD BUSINESS
PARK, TOTTON, SOUTHAMPTON, SO40 3YS, UNITED
KINGDOM

BOC GLASGOW, PRIESTLEY WAY, BOGLESKOLE ROAD,
CAMBUSLANG, GLASGOW, G72 7HN, UNITED KINGDOM

BOC THAME, CHINNOR ROAD, THAME, OX9 3NX, UNITED
KINGDOM

BOC MIDDLESBOROUGH, TEES DOCK ROAD,
GRANGETOWN, MIDDLESBOROUGH, TS6 7RT, UNITED
KINGDOM

BOC CRAWLEY, FLEMING WAY, CRAWLEY, RH10 2NH,
UNITED KINGDOM

BOC DERBY, RAYNESWAY, DERBY, DE21 7BD, UNITED
KINGDOM

BOC LIMITED, 28 DEER PARK ROAD, LONDON, SW19 3UF,
UNITED KINGDOM

BOC SCUNTHORPE, WARREN ROAD, SCUNTHORPE, DN15
6XH, UNITED KINGDOM

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

4: Legally registered address of authorisation holder

BOC LIMITED, FORGE, 43 CHURCH STREET WEST, WOKING,
GU21 6HT, 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

16/08/2022

9: Annexes attached

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC BELFAST, PRINCE REGENT ROAD, CASTLEREAGH, BELFAST, BT5 6RW, 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 [1.5.2] Secondary packaging [1.6] Quality control testing [1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC BRISTOL, WHITBY ROAD, BRISTOL, BS4 3QH, 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

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC WEMBLEY, EAST LANE, WEMBLEY, HA9 7PT, 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

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC MARGAM, LONGLANDS LANE, MARGAM, PORT TALBOT, SA13 2NS, UNITED KINGDOM

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

<p>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.2] Non-sterile products</p> <p>[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)</p> <p>[1.2.1.7] Medicinal gases</p> <p>[1.5] Packaging</p> <p>[1.5.1] Primary packaging</p> <p>[1.5.1.7] Medicinal gases</p> <p>[1.5.2] Secondary packaging</p> <p>[1.6] Quality control testing</p> <p>[1.6.3] Chemical/Physical</p>
--

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC BRINSWORTH, BAWTRY ROAD, BRINSWORTH, ROTHERHAM, S60 5NT, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

<p>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.2] Non-sterile products</p> <p>[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)</p> <p>[1.2.1.7] Medicinal gases</p> <p>[1.5] Packaging</p> <p>[1.5.1] Primary packaging</p> <p>[1.5.1.7] Medicinal gases</p> <p>[1.5.2] Secondary packaging</p> <p>[1.6] Quality control testing</p> <p>[1.6.3] Chemical/Physical</p>
--

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC WORSLEY, PRIESTLEY ROAD, WORSLEY, MANCHESTER, M28 2LX, 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
[1.5.2] Secondary packaging
[1.6] Quality control testing
[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC FAWLEY, CHARLESTON ROAD, HARDLEY, HYTHE, SOUTHAMPTON, SO45 3NX, 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
[1.5.2] Secondary packaging
[1.6] Quality control testing
[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC COVENTRY, TERRY ROAD, COVENTRY, CV1 2BE, 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 [1.5.2] Secondary packaging [1.6] Quality control testing [1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC PLYMOUTH, MAXWELL ROAD, PRINCE ROCK, PLYMOUTH, PL4 0RT, 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 [1.5.2] Secondary packaging [1.6] Quality control testing [1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC WOLVERHAMPTON, LOWER WALSALL STREET, WOLVERHAMPTON, WV1 2EP, 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 [1.5.2] Secondary packaging [1.6] Quality control testing [1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC MOTHERWELL, CHAPELKNOWE ROAD, CARFIN, MOTHERWELL, ML1 5LF, 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 [1.5.2] Secondary packaging [1.6] Quality control testing

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC LIMITED - HARLOW, UNIT D, RIVER WAY, HARLOW, CM20 2DP, 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 [1.4] Other products or manufacturing activity [1.4.1] Manufacture of: [1.4.1.3] Other Medicinal gases [1.5] Packaging [1.5.1] Primary packaging [1.5.1.7] Medicinal gases [1.5.2] Secondary packaging [1.6] Quality control testing [1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC TOTTON, 7/8 BRUNEL ROAD, WESTWOOD BUSINESS PARK, TOTTON, SOUTHAMPTON, SO40 3YS, 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

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC GLASGOW, PRIESTLEY WAY, BOGLESHOLE ROAD, CAMBUSLANG, GLASGOW, G72 7HN, 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

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC THAME, CHINNOR ROAD, THAME, OX9 3NX, 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

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC MIDDLESBOROUGH, TEES DOCK ROAD, GRANGETOWN, MIDDLESBROUGH, TS6 7RT, 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

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC CRAWLEY, FLEMING WAY, CRAWLEY, RH10 2NH, 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

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC DERBY, RAYNESWAY, DERBY, DE21 7BD, 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

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC LIMITED, 28 DEER PARK ROAD, LONDON, SW19 3UF, UNITED KINGDOM

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

<p>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.2] Non-sterile products</p> <p>[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)</p> <p>[1.2.1.7] Medicinal gases</p> <p>[1.5] Packaging</p> <p>[1.5.1] Primary packaging</p> <p>[1.5.1.7] Medicinal gases</p> <p>[1.5.2] Secondary packaging</p> <p>[1.6] Quality control testing</p> <p>[1.6.3] Chemical/Physical</p>
--

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC SCUNTHORPE, WARREN ROAD, SCUNTHORPE, DN15 6XH, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

<p>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.2] Non-sterile products</p> <p>[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)</p> <p>[1.2.1.7] Medicinal gases</p> <p>[1.5] Packaging</p> <p>[1.5.1] Primary packaging</p> <p>[1.5.1.7] Medicinal gases</p> <p>[1.5.2] Secondary packaging</p> <p>[1.6] Quality control testing</p> <p>[1.6.3] Chemical/Physical</p>
--

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BOC LIMITED, FORGE, 43 CHURCH STREET WEST, WOKING, GU21 6HT, 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