

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 735

2: Name of authorisation holder BOC LIMITED

3: Address(es) of manufacturing site(s) BOC LIMITED, 28 DEER PARK ROAD, LONDON, SW19 3UF, UNITED KINGDOM
BOC LIMITED, FORGE, 43 CHURCH STREET WEST, WOKING, GU21 6HT, UNITED KINGDOM

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 Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

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

8: Authorisation Date 14/11/2022

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal 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 2

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Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal 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