Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 18920

2: Name of authorisation holder BRACCO UK LIMITED

BRACCO UK LIMITED, MAGDALEN CENTRE, THE OXFORD

SCIENCE PARK, 1 ROBERT ROBINSON AVENUE, OXFORD, OX4

4GA, UNITED KINGDOM

BRACCO UK LIMITED, MAGDALEN CENTRE, THE OXFORD

4: Legally registered address of authorisation holder SCIENCE PARK, 1 ROBERT ROBINSON AVENUE, OXFORD, OX4

4GA, 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 16/01/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

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

Annex 1

Name and address of the site:

BRACCO UK LIMITED, MAGDALEN CENTRE, THE OXFORD SCIENCE PARK, 1 ROBERT ROBINSON AVENUE, OXFORD, OX4 4GA, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

Radiopharmaceuticals

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