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, UNIT 15, VALLEY BUSINESS CENTRE,

GORDON ROAD, HIGH WYCOMBE, HP13 6EQ, UNITED KINGDOM

BRACCO UK LIMITED, UNIT 15, VALLEY BUSINESS CENTRE,

GORDON ROAD, HIGH WYCOMBE, HP13 6EQ, 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

4: Legally registered address of authorisation holder

authorisation

Confidential

8: Authorisation Date 14/02/2022

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

Issue Date: 14 Feb 2022

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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