Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

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

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

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

8: Authorisation Date

9: Annexes attached

UK MIA(IMP) 11648

MERCK SERONO LIMITED

MERCK SERONO LIMITED, 5 NEW SQUARE, BEDFONT LAKES BUSINESS PARK, FELTHAM, TW14 8HA, UNITED KINGDOM

KINGDOM

MERCK SERONO LIMITED, 5 NEW SQUARE, BEDFONT LAKES BUSINESS PARK, FELTHAM, TW14 8HA, UNITED

KINGDOM

ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials)

Regulations 2004 [SI 2004/1031]

Confidential

18/09/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

MERCK SERONO LIMITED, 5 NEW SQUARE, BEDFONT LAKES BUSINESS PARK, FELTHAM, TW14 8HA, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[1.2] Non-sterile investigational medicinal products

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.2] Batch certification

[1.3.2.5] Biotechnology products

Issue Date: 18 Sep 2025

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.3] Biological medicinal products

[2.2.3.5] Biotechnology products

[2.3] Other Importation Activities

[2.3.4] Other

Importation of QP certified IMPs from a country on the approved country for import list



Manufacturer's Authorisation: UK MIA(IMP) 11648

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