

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 57419

2: Name of authorisation holder EMERGEX VACCINES HOLDING LIMITED

3: Address(es) of manufacturing site(s) EMERGEX VACCINES HOLDING LIMITED, 65 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RQ, UNITED KINGDOM

4: Legally registered address of authorisation holder EMERGEX VACCINES HOLDING LIMITED, 65 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RQ, 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 21/06/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

EMERGEX VACCINES HOLDING LIMITED, 65 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RQ, UNITED KINGDOM

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| 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 [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.4] Small volume liquids [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.6] Liquids for internal use |

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.6] Quality control testing

[1.6.3] Chemical/Physical

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

[2.2.1.2] Terminally sterilised

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing