Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 57419
2: Name of authorisation holder	GYLDEN PHARMA 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	GYLDEN PHARMA 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	15/12/2025
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

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

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[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

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