

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 18532
2: Name of authorisation holder	SEQIRUS VACCINES LIMITED
3: Address(es) of manufacturing site(s)	SEQIRUS VACCINES LIMITED , GASKILL ROAD, SPEKE, LIVERPOOL, L24 9GR, UNITED KINGDOM
4: Legally registered address of authorisation holder	SEQIRUS VACCINES LIMITED, GASKILL ROAD, SPEKE, LIVERPOOL, L24 9GR, 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	07/08/2023
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

SEQIRUS VACCINES LIMITED , GASKILL ROAD, SPEKE, LIVERPOOL, L24 9GR, 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) [1.1.1.6] Other aseptically prepared products Vaccines. [1.3] Biological investigational medicinal products [1.3.1] Biological medicinal products [1.3.1.2] Immunological products [1.3.1.6] Human or animal extracted products [1.3.1.8] Other biological medicinal products Vaccines

- [1.3.2] Batch certification
 - [1.3.2.2] Immunological products
 - [1.3.2.8] Other biological medicinal products
 - Vaccines

[1.4] Other investigational medicinal products or manufacturing activity

- [1.4.2] Sterilisation of active substances/excipients/finished products:
 - [1.4.2.1] Filtration

[1.5] Packaging

- [1.5.1] Primary packaging
 - [1.5.1.15] Other non-sterile medicinal products
 - Vaccines
- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [1.6.1] Microbiological: sterility
- [1.6.2] Microbiological: non-sterility
- [1.6.3] Chemical/Physical
- [1.6.4] Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

- [2.1.1] Microbiological: sterility
- [2.1.2] Microbiological: non-sterility
- [2.1.3] Chemical/Physical
- [2.1.4] Biological

[2.2] Batch certification of imported medicinal products

- [2.2.1] Sterile Products
 - [2.2.1.1] Aseptically prepared
- [2.2.3] Biological medicinal products
 - [2.2.3.2] Immunological products
 - [2.2.3.8] Other biological medicinal products
 - Vaccines

[2.3] Other Importation Activities

- [2.3.1] Site of Physical Importation
- [2.3.4] Other
 - EU Only Comparator Products for use in Clinical Trial Studies