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) 18532

SEQIRUS VACCINES LIMITED

SEQIRUS VACCINES LIMITED, GASKILL ROAD, SPEKE, LIVERPOOL, L24 9GR, UNITED KINGDOM

SEQIRUS VACCINES LIMITED, GASKILL ROAD, SPEKE, LIVERPOOL, L24 9GR, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials)
Regulations 2004 [SI 2004/1031]

Confidential

13/10/2025

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

Issue Date: 13 Oct 2025

[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 activitiy [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

Issue Date: 13 Oct 2025