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 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

Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

Confidential

18/06/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human 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 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 medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.3.1.8] Other biological medicinal products

Vaccines

Issue Date: 18 Jun 2025

[1.3.2] Batch certification [1.3.2.2] Immunological products [1.3.2.8] Other biological medicinal products Vaccines [1.4] Other 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 [1.5.1.17] 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 [2.2.1.2] Terminally sterilised [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

[2.3.3] Biological Active Substance

[2.3.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

Importation, testing and release of Neuraminidase inhibitor

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