

# 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** 18/06/2025

**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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.6 ] Other aseptically prepared products Vaccines. <b>[ 1.3 ] Biological investigational medicinal products</b> [ 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