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	13/10/2025
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)

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 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