

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 21659

2: Name of authorisation holder VALNEVA SCOTLAND LIMITED

3: Address(es) of manufacturing site(s) VALNEVA SCOTLAND LIMITED , OAKBANK PARK ROAD,
MID CALDER, LIVINGSTON, EH53 0TG, UNITED KINGDOM

4: Legally registered address of authorisation holder VALNEVA SCOTLAND LIMITED, OAKBANK PARK ROAD,
MID CALDER, LIVINGSTON, EH53 0TG, 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 21/11/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

VALNEVA SCOTLAND LIMITED , OAKBANK PARK ROAD, MID CALDER, LIVINGSTON, EH53 0TG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.1] Large volume liquids [1.3] Biological investigational medicinal products [1.3.1] Biological medicinal products [1.3.1.2] Immunological products [1.3.2] Batch certification [1.3.2.2] Immunological products [1.3.2.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activity

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

[1.4.2.1] Filtration

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological