

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|--|
| <b>1: Authorisation Number</b>  | UK MIA(IMP) 21659  |
| <b>2: Name of authorisation holder</b>  | VALNEVA SCOTLAND LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | VALNEVA SCOTLAND LIMITED , OAKBANK PARK ROAD, MID CALDER, LIVINGSTON, EH53 0TG, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | VALNEVA SCOTLAND LIMITED, OAKBANK PARK ROAD, MID CALDER, LIVINGSTON, EH53 0TG, UNITED KINGDOM  |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2  |
| <b>6: Legal Basis of authorisation</b>  | Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]        |
| <b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b> | Confidential   |
| <b>8: Authorisation Date</b>  | 12/02/2024   |
| <b>9: Annexes attached</b>  | 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

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|---|
| Human Investigational Medicinal Products  |
| Authorised Operations   |
| MANUFACTURING OPERATIONS (according to part 1)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 1.1.1.1 ] Large volume liquids<br><b>[ 1.3 ] Biological investigational medicinal products</b><br>[ 1.3.1 ] Biological medicinal products<br>[ 1.3.1.2 ] Immunological products<br>[ 1.3.2 ] Batch certification<br>[ 1.3.2.2 ] Immunological products<br>[ 1.3.2.5 ] Biotechnology products<br><b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b> |

[ 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