

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 44403

**2: Name of authorisation holder** PORTON BIOPHARMA LIMITED

**3: Address(es) of manufacturing site(s)** PORTON BIOPHARMA LIMITED, MANOR FARM ROAD,  
PORTON DOWN, SALISBURY, SP4 0JG, UNITED  
KINGDOM

**4: Legally registered address of authorisation holder** PORTON BIOPHARMA LIMITED, MANOR FARM ROAD,  
PORTON DOWN, SALISBURY, SP4 0JG, UNITED  
KINGDOM

**5: Scope of authorisation and dosage forms** ANNEX 1 and/ or ANNEX 2

**6: Legal Basis of authorisation** Regulation 17 of The Human Medicines Regulations 2012 (SI  
2012/1916)

**7: Name of responsible officer of the competent authority of the  
member state granting the manufacturing authorisation** Confidential

**8: Authorisation Date** 04/06/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**PORTON BIOPHARMA LIMITED, MANOR FARM ROAD, PORTON DOWN, SALISBURY, SP4 0JG, UNITED KINGDOM**

|                                                                                                                                                                                                                                                                                                                                                                                                         |
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| Human Medicinal Products                                                                                                                                                                                                                                                                                                                                                                                |
| Authorised Operations                                                                                                                                                                                                                                                                                                                                                                                   |
| MANUFACTURING OPERATIONS (according to part 1)                                                                                                                                                                                                                                                                                                                                                          |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 1.1.1.2 ] Lyophilisates<br>[ 1.1.1.4 ] Small volume liquids<br>[ 1.1.3 ] Batch certification<br><b>[ 1.3 ] Biological medicinal products</b><br>[ 1.3.1 ] Biological medicinal products<br>[ 1.3.1.2 ] Immunological products |

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.8 ] Other biological medicinal products

Botulinum Toxins and Toxoids Bacterial Enzymes (Erwinia L-asparaginase) Bacterial Toxoids

[ 1.3.2 ] Batch certification

[ 1.3.2.2 ] Immunological products

[ 1.3.2.5 ] Biotechnology products

**[ 1.4 ] Other 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