

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|                                                                                                                               |                                                                                               |
|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| <b>1: Authorisation Number</b>                                                                                                | UK MIA 44403                                                                                  |
| <b>2: Name of authorisation holder</b>                                                                                        | PORTON BIOPHARMA LIMITED                                                                      |
| <b>3: Address(es) of manufacturing site(s)</b>                                                                                | PORTON BIOPHARMA LIMITED, MANOR FARM ROAD,<br>PORTON DOWN, SALISBURY, SP4 0JG, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>                                                                  | PORTON BIOPHARMA LIMITED, MANOR FARM ROAD,<br>PORTON DOWN, SALISBURY, SP4 0JG, UNITED KINGDOM |
| <b>5: Scope of authorisation and dosage forms</b>                                                                             | ANNEX 1 and/ or ANNEX 2                                                                       |
| <b>6: Legal Basis of authorisation</b>                                                                                        | Regulation 17 of The Human Medicines Regulations 2012 (SI<br>2012/1916)                       |
| <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>                                                                                                  | 20/11/2024                                                                                    |
| <b>9: Annexes attached</b>                                                                                                    | 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<br>[ 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