

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 42195
2: Name of authorisation holder	PUBLIC HEALTH ENGLAND
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	PUBLIC HEALTH ENGLAND, 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	26/06/2018
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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.2] Lyophilisates [1.1.1.4] Small volume liquids [1.3] Biological medicinal products [1.3.1] Biological medicinal products [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

[1.4] Other products or manufacturing activity

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

[1.4.2.1] Filtration

[1.4.2.2] Dry heat

[1.4.2.3] Moist heat

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological