

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK ManA 18480

2: Name of authorisation holder FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED

3: Address(es) of manufacturing site(s) FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED,
BELASIS AVENUE, BILLINGHAM, TS23 1LH, UNITED
KINGDOM

4: Legally registered address of authorisation holder FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED,
BELASIS AVENUE, BILLINGHAM, TS23 1LH, UNITED
KINGDOM

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

6: Legal Basis of authorisation Regulation 5 of the current Veterinary Medicines Regulations

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

8: Authorisation Date 02/10/2026

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED, BELASIS AVENUE, BILLINGHAM, TS23 1LH, UNITED KINGDOM

Veterinary Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS 1. MANUFACTURING OPERATIONS [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 Manufacturing of recombinant protein intermediates and active pharmaceutical ingredients master/working cell banks, storage of these and samples for testing [1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological