

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 20377

2: Name of authorisation holder ALMAC CLINICAL SERVICES LIMITED

3: Address(es) of manufacturing site(s) ALMAC CLINICAL SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON, NORTHERN IRELAND, BT63 5PW, UNITED KINGDOM

4: Legally registered address of authorisation holder ALMAC CLINICAL SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON, NORTHERN IRELAND, BT63 5PW, 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 17/04/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ALMAC CLINICAL SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON, NORTHERN IRELAND, BT63 5PW, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.2] Non-sterile products [1.2.2] Batch certification [1.3] Biological medicinal products [1.3.2] Batch certification

- [1.3.2.1] Blood products
- [1.3.2.2] Immunological products
- [1.3.2.3] Cell therapy products
- [1.3.2.4] Gene therapy products
- [1.3.2.5] Biotechnology products
- [1.3.2.6] Human or animal extracted products