Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 20377

2: Name of authorisation holder ALMAC CLINICAL SERVICES LIMITED

ALMAC CLINICAL SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE,

9 CHARLESTOWN ROAD, CRAIGAVON, NORTHERN IRELAND, BT63

5PW, UNITED KINGDOM

ALMAC CLINICAL SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE,

4: Legally registered address of authorisation holder 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 authorisationRegulation 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

3: Address(es) of manufacturing site(s)

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

Issue Date: 17 Apr 2024

- [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

