Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 22774

2: Name of authorisation holder BIORELIANCE LIMITED

BIORELIANCE LIMITED, TODD CAMPUS, WEST OF

SCOTLAND SCIENCE PARK, GLASGOW, G20 0XA, UNITED

KINGDOM

BIORELIANCE LIMITED, TODD CAMPUS, WEST OF

SCOTLAND SCIENCE PARK, GLASGOW, G20 0XA, UNITED

KINGDOM

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

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

4: Legally registered address of authorisation holder

Confidential

8: Authorisation Date

6: Legal Basis of authorisation

04/06/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

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

Annex 1

Name and address of the site:

BIORELIANCE LIMITED, TODD CAMPUS, WEST OF SCOTLAND SCIENCE PARK, GLASGOW, G20 0XA, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Biological Active Starting Materials

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

Issue Date: 04 Jun 2025

[1.4.2.1] Filtration

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

