Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

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

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

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

8: Authorisation Date

9: Annexes attached

UK MIA 22774

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

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

26/06/2023

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

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:

[1.4.2.1] Filtration

[1.6] Quality control testing

Issue Date: 26 Jun 2023

- [1.6.1] Microbiological: sterility
- [1.6.2] Microbiological: non-sterility
- [1.6.3] Chemical/Physical
- [1.6.4] Biological

