# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number

UK MIA(IMP) 45317

2: Name of authorisation holder

XERIMIS LIMITED

XERIMIS LIMITED, UNIT A2 ACCESS TWELVE, STATION

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

ROAD, THEALE, READING, RG7 4PN, UNITED KINGDOM

4: Legally registered address of authorisation holder

XERIMIS LIMITED, UNIT A2 ACCESS TWELVE, STATION ROAD, THEALE, READING, RG7 4PN, UNITED KINGDOM

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

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials)

Regulations 2004 [SI 2004/1031]

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

8: Authorisation Date 25/05/2023

9: Annexes attached Annex 1 and/or Annex 2

## SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

XERIMIS LIMITED, UNIT A2 ACCESS TWELVE, STATION ROAD, THEALE, READING, RG7 4PN, UNITED KINGDOM

**Human Investigational Medicinal Products** 

**Authorised Operations** 

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

## Part 1 - MANUFACTURING OPERATIONS

## [ 1.3 ] Biological investigational medicinal products

[ 1.3.2 ] Batch certification

[ 1.3.2.2 ] Immunological products

[ 1.5 ] Packaging

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[ 2.2 ] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

Issue Date: 25 May 2023

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[ 2.2.3 ] Biological medicinal products

[2.2.3.1] Blood products

[ 2.2.3.2 ] Immunological products

[2.2.3.3] Cell therapy products

[2.2.3.4] Gene therapy products

[2.2.3.5] Biotechnology products

[ 2.2.3.6 ] Human or animal extracted products

# [ 2.3 ] Other Importation Activities

[2.3.1] Site of Physical Importation

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

[ 2.3.4 ] Other

Importation of QP certified IMPs from a country on the approved country for import list

Issue Date: 25 May 2023 Page 2 of 2 Manufacturer's Authorisation: UK MIA(IMP) 45317