

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|--|
| <b>1: Authorisation Number</b>  | UK MIA 45317   |
| <b>2: Name of authorisation holder</b>  | XERIMIS LIMITED  |
| <b>3: Address(es) of manufacturing site(s)</b>  | XERIMIS LIMITED, UNIT A2 ACCESS TWELVE, STATION ROAD, THEALE, READING, RG7 4PN, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | XERIMIS LIMITED, UNIT A2 ACCESS TWELVE, STATION ROAD, THEALE, READING, RG7 4PN, UNITED KINGDOM |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2  |
| <b>6: Legal Basis of authorisation</b>  | Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)                           |
| <b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b> | Confidential   |
| <b>8: Authorisation Date</b>  | 25/05/2023   |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2   |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

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

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| Human Medicinal Products   |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.3 ] Biological medicinal products</b><br>[ 1.3.2 ] Batch certification<br>[ 1.3.2.2 ] Immunological products<br><b>[ 1.5 ] Packaging</b><br>[ 1.5.2 ] Secondary packaging<br><b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b><br><b>[ 2.2 ] Batch certification of imported medicinal products</b><br>[ 2.2.1 ] Sterile Products<br>[ 2.2.1.1 ] Aseptically prepared |

[ 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