

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 17269

**2: Name of authorisation holder** PROTHERICS UK LIMITED

**3: Address(es) of manufacturing site(s)** PROTHERICS UK LIMITED, BLAENWAUN  
FFOSTRASOL, LLANDYSUL, SA44 5JT, UNITED  
KINGDOM

**4: Legally registered address of authorisation holder** PROTHERICS UK LIMITED, BLAENWAUN,  
FFOSTRASOL, LLANDYSUL, SA44 5JT, 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** Confidential

**8: Authorisation Date** 17/03/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**PROTHERICS UK LIMITED**, BLAENWAUN FFOSTRASOL, LLANDYSUL, SA44 5JT, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.1 ] Biological medicinal products [ 1.3.1.6 ] Human or animal extracted products [ 1.3.2 ] Batch certification [ 1.3.2.2 ] Immunological products

[ 1.3.2.5 ] Biotechnology products

**[ 1.4 ] Other investigational medicinal products or manufacturing activity**

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

[ 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

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.1 ] Microbiological: sterility

[ 2.1.2 ] Microbiological: non-sterility

[ 2.1.3 ] Chemical/Physical

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.1 ] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.5 ] Biotechnology products