

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)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [1.1.3] Batch certification [1.3] Biological investigational medicinal products [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