

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 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 Regulation 17 of The Human Medicines Regulations 2012
(SI 2012/1916)

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 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.6] Other aseptically prepared products formulated bulk product is manufactured at this site and transferred to an external contractor for sterile filtration, filling and lyophilisation. [1.3] Biological medicinal products [1.3.1] Biological medicinal products [1.3.1.6] Human or animal extracted products

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical