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	23/07/2024
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

[1.4] Other 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