Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 19819
2: Name of authorisation holder	BIOTEC SERVICES INTERNATIONAL LIMITED
3: Address(es) of manufacturing site(s)	BIOTEC SERVICES INTERNATIONAL LIMITED, UNITS 2100, 2110, 2120, 2130, 2010, 2430 AND 2500, PHASE 18, CENTRAL PARK, BRIDGEND INDUSTRIAL ESTATE, BRIDGEND, CF31 3TY, UNITED KINGDOM BIOTEC SERVICES INTERNATIONAL LIMITED, BIOTEC HOUSE, CENTRAL PARK, WESTERN AVENUE, BRIDGEND INDUSTRIAL ESTATE, BRIDGEND, CF31 3RT, UNITED KINGDOM
4: Legally registered address of authorisation holder	BIOTEC SERVICES INTERNATIONAL LIMITED, BIOTEC HOUSE, CENTRAL PARK, WESTERN AVENUE, BRIDGEND INDUSTRIAL ESTATE, BRIDGEND, CF31 3RT, 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	01/05/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BIOTEC SERVICES INTERNATIONAL LIMITED, UNITS 2100, 2110, 2120, 2130, 2010, 2430 AND 2500, PHASE 18, CENTRAL PARK, BRIDGEND INDUSTRIAL ESTATE, BRIDGEND, CF31 3TY, 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

[1.2] Non-sterile investigational medicinal products

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.2] Batch certification

[1.3.2.1] Blood products

[1.3.2.2] Immunological products

[1.3.2.3] Cell therapy products

[1.3.2.4] Gene therapy products

[1.3.2.5] Biotechnology products

[1.3.2.6] Human or animal extracted products

[1.3.2.7] Tissue Engineered Products

[1.5] Packaging

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[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

[2.2.3.7] Tissue Engineered Products

[2.2.3.8] Other biological medicinal products

Tissue engineered products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Importation of QP certified IMPs from a country on the approved country for import list

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BIOTEC SERVICES INTERNATIONAL LIMITED, BIOTEC HOUSE, CENTRAL PARK, WESTERN AVENUE, BRIDGEND INDUSTRIAL ESTATE, BRIDGEND, CF31 3RT, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

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IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

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