

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 19819
<b>2: Name of authorisation holder</b>	BIOTEC SERVICES INTERNATIONAL LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	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
<b>4: Legally registered address of authorisation holder</b>	BIOTEC SERVICES INTERNATIONAL LIMITED, BIOTEC HOUSE, CENTRAL PARK, WESTERN AVENUE, BRIDGEND INDUSTRIAL ESTATE, BRIDGEND, CF31 3RT, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	12/01/2021
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

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 Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> [ 1.1 ] Sterile Products [ 1.1.3 ] Batch certification [ 1.2 ] Non-sterile products

[ 1.2.2 ] Batch certification

**[ 1.3 ] Biological medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.1 ] Blood products

[ 1.3.1.2 ] Immunological products

[ 1.3.1.3 ] Cell therapy products

[ 1.3.1.4 ] Gene therapy products

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.6 ] Human or animal extracted 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

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

Human 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 Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile products</b> [ 1.2.2 ] Batch certification <b>[ 1.3 ] Biological medicinal products</b> [ 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 <b>Special Requirements</b> Tissue engineered product [ 1.3.2.8 ] Other biological medicinal products Tissue engineered products <b>[ 1.5 ] Packaging</b> [ 1.5.2 ] Secondary packaging <b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b> <b>[ 2.2 ] Batch certification of imported medicinal products</b> [ 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 <b>[ 2.3 ] Other Importation Activities</b> [ 2.3.1 ] Site of Physical Importation