

# 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, BIOTEC HOUSE,<br>CENTRAL PARK, WESTERN AVENUE, BRIDGEND INDUSTRIAL ESTATE,<br>BRIDGEND, CF31 3RT, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder                                                                        | BIOTEC SERVICES INTERNATIONAL LIMITED, BIOTEC HOUSE,<br>CENTRAL PARK, WESTERN AVENUE, BRIDGEND INDUSTRIAL ESTATE,<br>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<br>2004/1031]                                                              |
| 7: Name of responsible officer of the competent<br>authority of the member state granting the<br>manufacturing authorisation | Confidential                                                                                                                                            |
| 8: Authorisation Date                                                                                                        | 22/08/2025                                                                                                                                              |
| 9: Annexes attached                                                                                                          | Annex 1 and/or Annex 2                                                                                                                                  |

### 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                                                                                                                  |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                              |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 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

[ 2.3.3 ] Biological Active Substance

[ 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**, 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

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| Authorised Operations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <p>MANUFACTURING OPERATIONS (according to part 1)</p> <p>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.1 ] Sterile Investigational Medicinal Products</b></p> <p>[ 1.1.3 ] Batch certification</p> <p><b>[ 1.2 ] Non-sterile investigational medicinal products</b></p> <p>[ 1.2.2 ] Batch certification</p> <p><b>[ 1.3 ] Biological investigational medicinal products</b></p> <p>[ 1.3.2 ] Batch certification</p> <p>[ 1.3.2.1 ] Blood products</p> <p>[ 1.3.2.2 ] Immunological products</p> <p>[ 1.3.2.3 ] Cell therapy products</p> <p>[ 1.3.2.4 ] Gene therapy products</p> <p>[ 1.3.2.5 ] Biotechnology products</p> <p>[ 1.3.2.6 ] Human or animal extracted products</p> <p>[ 1.3.2.7 ] Tissue Engineered Products</p> <p><b>[ 1.5 ] Packaging</b></p> <p>[ 1.5.2 ] Secondary packaging</p> <p><b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b></p> <p><b>[ 2.2 ] Batch certification of imported medicinal products</b></p> <p>[ 2.2.1 ] Sterile Products</p> <p>[ 2.2.1.1 ] Aseptically prepared</p> <p>[ 2.2.1.2 ] Terminally sterilised</p> <p>[ 2.2.2 ] Non-sterile products</p> <p>[ 2.2.3 ] Biological medicinal products</p> <p>[ 2.2.3.1 ] Blood products</p> <p>[ 2.2.3.2 ] Immunological products</p> <p>[ 2.2.3.3 ] Cell therapy products</p> <p>[ 2.2.3.4 ] Gene therapy products</p> <p>[ 2.2.3.5 ] Biotechnology products</p> <p>[ 2.2.3.6 ] Human or animal extracted products</p> <p>[ 2.2.3.7 ] Tissue Engineered Products</p> <p>[ 2.2.3.8 ] Other biological medicinal products</p> <p>Tissue engineered products</p> <p><b>[ 2.3 ] Other Importation Activities</b></p> <p>[ 2.3.1 ] Site of Physical Importation</p> <p>[ 2.3.2 ] Importation of Intermediate which undergoes further processing</p> <p>[ 2.3.3 ] Biological Active Substance</p> <p>[ 2.3.4 ] Other</p> <p>Importation of QP certified IMPs from a country on the approved country for import list</p> |