

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 40211

**2: Name of authorisation holder** SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED  
SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, THE BRUCE BUILDING, CASTLE BUSINESS PARK, STIRLING, FK9 4TS, UNITED KINGDOM

**3: Address(es) of manufacturing site(s)** SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, SCION HOUSE, STIRLING UNIVERSITY INNOVATION PARK, STIRLING, FK9 4NF, UNITED KINGDOM

**4: Legally registered address of authorisation holder** SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, UNIT 10, SCION HOUSE, STIRLING UNIVERSITY INNOVATION PARK, STIRLING, FK9 4NF, 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** 29/07/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED**, THE BRUCE BUILDING, CASTLE BUSINESS PARK, STIRLING, FK9 4TS, 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> <b>[ 1.1 ] Sterile Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)

[ 1.1.1.4 ] Small volume liquids

**Special Requirements**

Cytotoxics

[ 1.1.1.6 ] Other aseptically prepared products

Suspensions

**Special Requirements**

Cytotoxics

**[ 1.3 ] Biological medicinal products**

[ 1.3.1 ] Biological medicinal 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

[ 1.3.1.8 ] Other biological medicinal products

Plasmid, DNA, RNA, peptides, proteins and antibody products.

**Special Requirements**

Cytotoxics

**[ 1.4 ] Other products or manufacturing activity**

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.4 ] Gene therapy products

**[ 2.3 ] Other Importation Activities**

[ 2.3.1 ] Site of Physical Importation

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

**SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED**, SCION HOUSE, STIRLING UNIVERSITY INNOVATION PARK, STIRLING,  
FK9 4NF, UNITED KINGDOM

Human 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 Products**

- [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)
  - [ 1.1.1.2 ] Lyophilisates
  - [ 1.1.1.4 ] Small volume liquids

### **Special Requirements**

Cytotoxics

### **[ 1.3 ] Biological medicinal products**

- [ 1.3.1 ] Biological medicinal products
  - [ 1.3.1.4 ] Gene therapy products
  - [ 1.3.1.5 ] Biotechnology products

### **[ 1.4 ] Other products or manufacturing activity**

- [ 1.4.2 ] Sterilisation of active substances/excipients/finished products:
  - [ 1.4.2.1 ] Filtration

## **Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

### **[ 2.2 ] Batch certification of imported medicinal products**

- [ 2.2.3 ] Biological medicinal products
  - [ 2.2.3.4 ] Gene therapy products

### **[ 2.3 ] Other Importation Activities**

- [ 2.3.1 ] Site of Physical Importation
- [ 2.3.2 ] Importation of Intermediate which undergoes further processing