

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |   |
|---|---|
| <b>1: Authorisation Number</b>  | UK MIA 40211  |
| <b>2: Name of authorisation holder</b>  | SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, SCION HOUSE, STIRLING UNIVERSITY INNOVATION PARK, STIRLING, FK9 4NF, UNITED KINGDOM          |
| <b>4: Legally registered address of authorisation holder</b>  | SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, UNIT 10, SCION HOUSE, STIRLING UNIVERSITY INNOVATION PARK, STIRLING, FK9 4NF, 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>  | 29/11/2024  |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2  |

### 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)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)   |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 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