

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |  |
|---|--|
| <b>1: Authorisation Number</b>  | UK MIA 31  |
| <b>2: Name of authorisation holder</b>  | ROCHE PRODUCTS LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | ROCHE PRODUCTS LIMITED, 6 FALCON WAY, SHIRE PARK,<br>WELWYN GARDEN CITY, AL7 1TW, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | ROCHE PRODUCTS LIMITED, 6 FALCON WAY, SHIRE PARK,<br>WELWYN GARDEN CITY, AL7 1TW, 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<br>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>  | 01/07/2024   |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2   |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**ROCHE PRODUCTS LIMITED**, 6 FALCON WAY, SHIRE PARK, WELWYN GARDEN CITY, AL7 1TW, 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>[ 1.1 ] <b>Sterile Products</b><br>[ 1.1.3 ] Batch certification<br>[ 1.2 ] <b>Non-sterile products</b><br>[ 1.2.2 ] Batch certification<br>[ 1.3 ] <b>Biological medicinal products</b><br>[ 1.3.2 ] Batch certification<br>[ 1.3.2.5 ] Biotechnology products<br><b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b><br>[ 2.2 ] <b>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

[ 2.2.3.5 ] Biotechnology products

**[ 2.3 ] Other Importation Activities**

[ 2.3.5] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)