# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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

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|---|
| Human Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.1 ] Sterile Products**

[ 1.1.3 ] Batch certification

**[ 1.2 ] Non-sterile products**

[ 1.2.2 ] Batch certification

**[ 1.3 ] Biological medicinal products**

[ 1.3.2 ] Batch certification

[ 1.3.2.5 ] Biotechnology products

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

[ 2.2.3.5 ] Biotechnology products

**[ 2.3 ] Other Importation Activities**

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