# Medicines and Healthcare products Regulatory Agency

#### MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

8: Authorisation Date

9: Annexes attached

UK MIA 31

ROCHE PRODUCTS LIMITED

ROCHE PRODUCTS LIMITED, 6 FALCON WAY, SHIRE PARK, WELWYN GARDEN CITY, AL7 1TW, UNITED KINGDOM

ROCHE PRODUCTS LIMITED, 6 FALCON WAY, SHIRE PARK, WELWYN GARDEN CITY, AL7 1TW, UNITED

KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

28/10/2025

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)

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

Issue Date: 28 Oct 2025

## 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)



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Page 2 of 2

Issue Date: 28 Oct 2025