Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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	29/04/2025
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

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

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)