Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 39
2: Name of authorisation holder	UCB PHARMA LIMITED
3: Address(es) of manufacturing site(s)	UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, SL1 3WE, UNITED KINGDOM UCB PHARMA LIMITED, WINDLESHAM CAMPUS, SUNNINGHILL ROAD, WINDLESHAM, GU20 6PP, UNITED KINGDOM
4: Legally registered address of authorisation holder	UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, SL1 3WE, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	21/08/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, SL1 3WE, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.4] Other

Importation of QP-certified IMPs from a country on the approved country for import list

Any restrictions or clarifying remarks

QP Valentine Hecq is included on this licence solely for the oversight of imported IMPs following certification in an approved country in accordance with the provisions of Regulation 43(1) of UK SI 2004/1031 (as amended). Valentine Hecq may not undertake QP certification of other activities performed under this MIA(IMP).

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

UCB PHARMA LIMITED, WINDLESHAM CAMPUS, SUNNINGHILL ROAD, WINDLESHAM, GU20 6PP, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS
[1.2] Non-sterile investigational medicinal products
[1.2.2] Batch certification
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS
[2.2] Batch certification of imported medicinal products
[2.2.2] Non-sterile products