

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 59204
2: Name of authorisation holder	HITECH HEALTH (UK) LIMITED
3: Address(es) of manufacturing site(s)	HITECH HEALTH UK LIMITED, NO.2 GLASSHOUSE- 2S9, ALDERLEY PARK, CONGLETON ROAD, NETHER ALDERLEY, MACCLESFIELD, SK10 4ZE, UNITED KINGDOM
4: Legally registered address of authorisation holder	HITECH HEALTH (UK) LIMITED, NO.2 GLASSHOUSE- 2S9, ALDERLEY PARK, CONGLETON ROAD, NETHER ALDERLEY, MACCLESFIELD, SK10 4ZE, 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	15/01/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

HITECH HEALTH UK LIMITED, NO.2 GLASSHOUSE- 2S9, ALDERLEY PARK, CONGLETON ROAD, NETHER ALDERLEY, MACCLESFIELD, SK10 4ZE, 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
[1.1] Sterile Investigational Medicinal Products
[1.1.3] Batch certification
[1.2] Non-sterile investigational medicinal products
[1.2.2] Batch certification
[1.3] Biological investigational medicinal products

- [1.3.2] Batch certification
- [1.3.2.4] Gene therapy products
- Special Requirements**
- Live Cells
- [1.3.2.5] Biotechnology products
- Special Requirements**
- Live Cells

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
 - [2.2.3.3] Cell therapy products
 - [2.2.3.4] Gene therapy products
 - [2.2.3.5] Biotechnology 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