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

HITECH HEALTH UK LIMITED, NO.2 GLASSHOUSE- 2S9, ALDERLEY

3: Address(es) of manufacturing site(s) PARK, CONGLETON ROAD, NETHER ALDERLEY, MACCLESFIELD,

SK10 4ZE, UNITED KINGDOM

HITECH HEALTH (UK) LIMITED, NO.2 GLASSHOUSE- 2S9, ALDERLEY

4: Legally registered address of authorisation holder 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 09/08/2024

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

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

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

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.3] Cell therapy products

[2.2.3.4] Gene therapy products

Issue Date: 09 Aug 2024

[2.3] Other Importation Activities

[2.3.4] Other

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

