

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 59204
<b>2: Name of authorisation holder</b>	HITECH HEALTH (UK) LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	HITECH HEALTH UK LIMITED, NO.2 GLASSHOUSE- 2S9, ALDERLEY PARK, CONGLETON ROAD, NETHER ALDERLEY, MACCLESFIELD, SK10 4ZE, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	HITECH HEALTH (UK) LIMITED, NO.2 GLASSHOUSE- 2S9, ALDERLEY PARK, CONGLETON ROAD, NETHER ALDERLEY, MACCLESFIELD, SK10 4ZE, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	09/08/2024
<b>9: Annexes attached</b>	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 <b>[ 2.2 ] Batch certification of imported medicinal products</b> [ 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

[ 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'

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA