# 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** | 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

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|---|
| 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

[ 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'