

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|--|
| <b>1: Authorisation Number</b>  | UK MIA(IMP) 53095  |
| <b>2: Name of authorisation holder</b>  | MERCK SHARP & DOHME (UK) LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | MERCK SHARP & DOHME (UK) LIMITED, 120<br>MOORGATE, LONDON, EC2M 6UR, UNITED KINGDOM        |
| <b>4: Legally registered address of authorisation holder</b>  | MERCK SHARP & DOHME (UK) LIMITED, 120<br>MOORGATE, LONDON, EC2M 6UR, 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)<br>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>  | 26/05/2023   |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2   |

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**MERCK SHARP & DOHME (UK) LIMITED, 120 MOORGATE, LONDON, EC2M 6UR, UNITED KINGDOM**

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| Human Investigational Medicinal Products   |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br>[ 1.1 ] <b>Sterile Investigational Medicinal Products</b><br>[ 1.1.3 ] Batch certification<br>[ 1.2 ] <b>Non-sterile investigational medicinal products</b><br>[ 1.2.2 ] Batch certification<br>[ 1.3 ] <b>Biological investigational medicinal products</b><br>[ 1.3.2 ] Batch certification<br>[ 1.3.2.2 ] Immunological products<br>[ 1.3.2.4 ] Gene therapy products<br>[ 1.3.2.5 ] Biotechnology products |

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

[ 2.2.3.2 ] Immunological 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 IMP's from a country on the approved country for import list