

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|--|
| <b>1: Authorisation Number</b>  | UK MIA(IMP) 25274  |
| <b>2: Name of authorisation holder</b>  | CATALENT CTS (EDINBURGH) LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | CATALENT CTS (EDINBURGH) LIMITED, UNIT 1 INCHWOOD PARK, BATHGATE, EH48 2FY, UNITED KINGDOM   |
| <b>4: Legally registered address of authorisation holder</b>  | CATALENT CTS (EDINBURGH) LIMITED, FRANKLAND ROAD, BLAGROVE, SWINDON, SN5 8YG, 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>  | 10/12/2021   |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2   |

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**CATALENT CTS (EDINBURGH) LIMITED**, UNIT 1 INCHWOOD PARK, BATHGATE, EH48 2FY, 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><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.3 ] Batch certification<br><b>[ 1.2 ] Non-sterile investigational medicinal products</b><br>[ 1.2.2 ] Batch certification<br><b>[ 1.3 ] Biological investigational medicinal products</b><br>[ 1.3.2 ] Batch certification<br>[ 1.3.2.1 ] Blood products<br>[ 1.3.2.2 ] Immunological products<br>[ 1.3.2.3 ] Cell therapy products |

- [ 1.3.2.4 ] Gene therapy products
- [ 1.3.2.5 ] Biotechnology products
- [ 1.3.2.6 ] Human or animal extracted products

#### **[ 1.5 ] Packaging**

- [ 1.5.1 ] Primary packaging
  - [ 1.5.1.1 ] Capsules, hard shell
  - [ 1.5.1.2 ] Capsules, soft shell
  - [ 1.5.1.3 ] Chewing gums
  - [ 1.5.1.4 ] Impregnated matrices
  - [ 1.5.1.8 ] Other solid dosage forms
  - [ 1.5.1.11 ] Semi-solids
  - [ 1.5.1.12 ] Suppositories
  - [ 1.5.1.13 ] Tablets
  - [ 1.5.1.14 ] Transdermal patches
  - [ 1.5.1.15 ] Other non-sterile medicinal products
    - Cytostatics, cytotoxics, hormone products may undergo primary packaging, pessaries
- [ 1.5.2 ] Secondary packaging

#### **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
  - [ 2.2.3.1 ] Blood products
  - [ 2.2.3.2 ] Immunological products
  - [ 2.2.3.3 ] Cell therapy products
  - [ 2.2.3.4 ] Gene therapy products
  - [ 2.2.3.5 ] Biotechnology products
  - [ 2.2.3.6 ] Human or animal extracted products

#### **[ 2.3 ] Other Importation Activities**

- [ 2.3.1 ] Site of Physical Importation
- [ 2.3.2 ] Importation of Intermediate which undergoes further processing
- [ 2.3.4 ] Other
  - Importation of QP-certified IMPs from a country on the approved country for import list