

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 25274

**2: Name of authorisation holder** CATALENT CTS (EDINBURGH) LIMITED

**3: Address(es) of manufacturing site(s)** CATALENT CTS (EDINBURGH) LIMITED, UNIT 1  
INCHWOOD PARK, BATHGATE, EH48 2FY, UNITED  
KINGDOM

**4: Legally registered address of authorisation holder** CATALENT CTS (EDINBURGH) LIMITED, FRANKLAND  
ROAD, BLAGROVE, SWINDON, SN5 8YG, 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** 10/12/2021

**9: Annexes attached** 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

Human Investigational Medicinal Products
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Authorised Operations
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MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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#### Part 1 - MANUFACTURING OPERATIONS

##### [ 1.1 ] Sterile Investigational Medicinal Products

[ 1.1.3 ] Batch certification

##### [ 1.2 ] Non-sterile investigational medicinal products

[ 1.2.2 ] Batch certification

##### [ 1.3 ] Biological investigational medicinal products

[ 1.3.2 ] Batch certification

[ 1.3.2.1 ] Blood products

- [ 1.3.2.2 ] Immunological products
- [ 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