

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 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, UNIT 1 INCHWOOD PARK, BATHGATE, EH48 2FY, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<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>	07/10/2021
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**CATALENT CTS (EDINBURGH) LIMITED**, UNIT 1 INCHWOOD PARK, BATHGATE, EH48 2FY, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile products</b> [ 1.2.2 ] Batch certification <b>[ 1.3 ] Biological medicinal products</b> [ 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**

- [ 1.5.2 ] 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