# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 51381

2: Name of authorisation holder ROYLANCE STABILITY STORAGE LIMITED

ROYLANCE STABILITY STORAGE LIMITED, BIOCITY

SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED

**KINGDOM** 

ROYLANCE STABILITY STORAGE LIMITED, BIOCITY

4: Legally registered address of authorisation holder SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED

**KINGDOM** 

Confidential

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

ing the manufacturing authorisation

8: Authorisation Date 31/01/2024

9: Annexes attached Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

3: Address(es) of manufacturing site(s)

#### Annex 2

Name and address of the site:

ROYLANCE STABILITY STORAGE LIMITED, BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED KINGDOM

**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

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[ 2.2.3.2 ] Immunological products

[2.2.3.3] Cell therapy products

Issue Date: 31 Jan 2024

- [ 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

