

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 37245
<b>2: Name of authorisation holder</b>	MYONEX LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	MYONEX LIMITED, 1 MEER END, BIRSTALL, LEICESTER, LE4 3EH, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	MYONEX LIMITED, 1 MEER END, BIRSTALL, LEICESTER, LE4 3EH, 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>	10/06/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**MYONEX LIMITED**, 1 MEER END, BIRSTALL, LEICESTER, LE4 3EH, UNITED KINGDOM

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

[ 2.2.3.2 ] Immunological 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

[ 2.3.4 ] Other

Importation of QP certified IMPs from a country on the