

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 13485
<b>2: Name of authorisation holder</b>	MW ENCAP LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	MW ENCAP LIMITED, UNITS 1-8, OAKBANK PARK WAY, OAKBANK INDUSTRIAL ESTATE, MID CALDER, LIVINGSTON, EH53 0TH, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	MW ENCAP LIMITED, UNITS 1-8, OAKBANK PARK WAY, OAKBANK INDUSTRIAL ESTATE, MID CALDER, LIVINGSTON, EH53 0TH, 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>	23/03/2023
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**MW ENCAP LIMITED**, UNITS 1-8, OAKBANK PARK WAY, OAKBANK INDUSTRIAL ESTATE, MID CALDER, LIVINGSTON, EH53 0TH, 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> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.1 ] Capsules, hard shell [ 1.2.1.15 ] Other non-sterile medicinal products Liquid fill capsules of Cytotoxics. Packing for open labelled clinical studies only (no blinding) <b>[ 1.3 ] Biological investigational medicinal products</b>

- [ 1.3.1 ] Biological medicinal products
- [ 1.3.1.5 ] Biotechnology products
- [ 1.3.1.6 ] Human or animal extracted products

**[ 1.5 ] Packaging**

- [ 1.5.1 ] Primary packaging
  - [ 1.5.1.1 ] Capsules, hard shell
  - [ 1.5.1.6 ] Liquids for internal use
  - [ 1.5.1.8 ] Other solid dosage forms
  - [ 1.5.1.11 ] Semi-solids
  - [ 1.5.1.13 ] Tablets
  - [ 1.5.1.15 ] Other non-sterile medicinal products
    - Liquid fill capsules of Cytotoxics

**[ 1.6 ] Quality control testing**

- [ 1.6.2 ] Microbiological: non-sterility
- [ 1.6.3 ] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

**[ 2.1 ] Quality control testing of imported medicinal products**

- [ 2.1.3 ] Chemical/Physical

**[ 2.2 ] Batch certification of imported medicinal products**

- [ 2.2.2 ] Non-sterile products

**[ 2.3 ] Other Importation Activities**

- [ 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