# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

| | |
|---|---|
| **1: Authorisation Number** | UK MIA 13485 |
| **2: Name of authorisation holder** | MW ENCAP LIMITED |
| **3: Address(es) of manufacturing site(s)** | MW ENCAP LIMITED, UNITS 1-8, OAKBANK PARK WAY, OAKBANK INDUSTRIAL ESTATE, MID CALDER, LIVINGSTON, EH53 0TH, UNITED KINGDOM |
| **4: Legally registered address of authorisation holder** | MW ENCAP LIMITED, UNITS 1-8, OAKBANK PARK WAY, OAKBANK INDUSTRIAL ESTATE, MID CALDER, LIVINGSTON, EH53 0TH, UNITED KINGDOM |
| **5: Scope of authorisation and dosage forms** | ANNEX 1 and/ or ANNEX 2 |
| **6: Legal Basis of authorisation** | Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916) |
| **7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation** | Confidential |
| **8: Authorisation Date** | 06/11/2026 |
| **9: Annexes attached** | Annex 1 and/or Annex 2 |

**SCOPE OF AUTHORISATION**

**Annex 1**

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 Medicinal Products |
|---|

| Authorised Operations |
|---|
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.2 ] Non-sterile products**

[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 1.2.1.1 ] Capsules, hard shell

[ 1.2.1.17 ] Other non-sterile medicinal products

Larger scale manufacture of Cytotoxics in dedicated high containment facilities. Initial dispensing of drug substance is carried out in an isolation cabinet. Packaging: Strip and/or blister packing

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[ 1.2.2 ] Batch certification

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 1.5.1.17 ] Other non-sterile medicinal products
Cytotoxics

[ 1.5.2 ] Secondary packaging

**[ 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

**[ 2.3 ] Other Importation Activities**

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

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