MINISTRY for HEALTH and ACTIVE AGEING
15, PALAZZO CASTELLANIA, MERCHANTS STREET, VALLETTA, MALTA

Manufacturing/Importation Licence[12]

1) Authorisation number	**ML013 (1st variation)**
2) Name of authorisation holder	**Pharmadox Healthcare Ltd**
2a) Alternative name of authorisation holder (optional)	**N/A**
3) Address(es) of manufacturing site(s) (All authorised sites should be listed if not covered by separate licences)	**KW20A, Kordin Industrial Park Paola PLA3000, Malta** **KKW46, Kordin Industrial Park Paola PLA3000, Malta** **HHF 303, Hal Far Industrial Estate , Hal Far Birzebbugia BBG3000**
3a) Additional details on units inspected of manufacturing site(s) address(es) (optional)	**N/A**
4) Legally registered address of authorisation holder	**KW20A, Kordin Industrial Park Paola PLA3000, Malta**
4a) Additional details on units inspected of legally registered address (optional)	**N/A**
5) Scope of authorisation and dosage forms	**ANNEX 1**
6) Legal basis of authorisation	**Directive 2001/83/EC Title IV Art 40** **Directive 2001/20/EC Art 13** **Regulation (EU) No 536/2014 Art 61** **Medicines Act 2003 Part III Title II Art 37** **Legal Notice 490 of 2004 Regulation 13 & 14** **Legal Notice 119 of 2006 regulation 7** **Legal Notice 381 of 2005 under Medicines Act 2003 regulation 3(3)**
7) Name of Responsible officer of the Competent authority of the member State granting the manufacturer's licence	**Prof Charmaine Gauci** ***[1]Licensing Authority**
8) Signature	

Office of the Superintendent of Pub[illegible]
Out-Patients Dept. Level 1, St. Luke's Hospital Gwardamangia
t +356 25953302/3 e sph.health@gov.mt

9) Date of issue **2nd April 2026**

10) Validity: **Valid till 19th December 2028**

[1] The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC as amended and Article 88(1) of Regulation (EU) 2019/6, shall also be required for imports coming from third countries into a Member State

[2] Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation

10) This Licence shall be governed by, and construed in accordance with, the laws of Malta. Any dispute arising out of or in connection with this Licence shall be subject to the exclusive jurisdiction of the courts of Malta.

11) Annexes attached: Annex 1 and/or Annex 2

Optional annexes as required:

Annex 3 - Addresses of Contracting Manufacturing Site(s)

Annex 4 - Addresses of Contract Laboratories

Annex 5 - Name of Qualified Person/s

Annex 6 - Name of responsible persons

Annex 7 - Date of inspection on which authorisation granted, scope of last inspection

Annex 8 – (Manufactured/imported products authorised)

Scope of Authorisation

ANNEX 1

Name and address of the site:

Pharmadox Healthcare Ltd
KW20A Kordin Industrial Park, Paola PLA3000, Malta

Human Medicinal Products

Authorised Operations

1. Manufacturing Operations (according to part 1)
2. Importation of Medicinal Products (according to part 2)

Part 1 – MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.3 *Batch certification*

1.2 Non-sterile products

1.2.2 *Batch certification*

1.5 Packaging

1.5.2 Secondary packing

1.6 Quality control testing

1.6.1 Microbiological: sterility
1.6.2 Microbiological: non-sterility
1.6.3 Chemical/Physical
1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

Re. 1.6.4: Biological testing is restricted to tests utilising materials of biological origin and the use of live cultured animal cells.

Part 2 – IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.1 Microbiological: sterility
2.1.2 Microbiological: non-sterility
2.1.3 Chemical/Physical
2.1.4 Biological

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

2.3 **Other importation activities** (any other importation activity that is not covered above)

2.3.1 Site of physical importation

Any restrictions or clarifying remarks related to the scope of these importing operations

Re. 2.1.4: Biological testing is restricted to tests utilising materials of biological origin and the use of live cultured animal cells.

ANNEX 1

Name and address of the site:

Pharmadox Healthcare Ltd
KKW46 Kordin Industrial Park, Paola PLA3000, Malta

Human Medicinal Products

Authorised Operations

1. Manufacturing Operations (according to part 1)
2. Importation of Medicinal Products (according to part 2)

Part 1 – MANUFACTURING OPERATIONS

1.4 Other products of manufacturing activity

1.4.3 *Other – Storage of medicinal products*

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

Climatic chambers are also present at this site.

ANNEX 1

Name and address of the site:
HHF 303, Hal Far Industrial Estate ,
Hal Far Birzebbugia BBG3000, Malta

Human Medicinal Products

Authorised Operations

3. Manufacturing Operations (according to part 1)
4. Importation of Medicinal Products (according to part 2)

Part 1 – MANUFACTURING OPERATIONS

1.5 Other products of manufacturing activity

1.4.3 *Other – Storage of medicinal products*

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

None

ANNEX 2

Name and address of the site:

Pharmadox Healthcare Ltd
KW20A Kordin Industrial Park, Paola PLA3000, Malta

Human Investigational Medicinal Products

Authorised Operations

1. Manufacturing Operations of Investigational Medicinal Products (according to part 1)
2. Importation of Investigational Medicinal Products (according to part 2)

Part 1 – MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.1 Sterile investigational medicinal products

1.1.3 *Batch certification*

1.2 Non-sterile investigational medicinal products

1.2.2 *Batch certification*

1.6 Packaging

1.5.2 Secondary packing

1.7 Quality control testing

1.7.1 Microbiological: sterility
1.7.2 Microbiological: non-sterility
1.7.3 Chemical/Physical
1.7.4 Biological

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

Re. 1.6.4: Biological testing is restricted to tests utilising materials of biological origin and the use of live cultured animal cells.

Part 2 – IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

2.1 Quality control testing of imported investigational medicinal products

2.1.1 Microbiological: sterility
2.1.2 Microbiological: non-sterility
2.1.3 Chemical/Physical
2.1.4 Biological

2.2 Batch certification of imported investigational 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

2.3 Other importation activities

2.3.1 Site of physical importation

Any restrictions or clarifying remarks related to the scope of these importing operations

Re. 2.1.4: Biological testing is restricted to tests utilising materials of biological origin and the use of live cultured animal cells.

ANNEX 4

Address(es) of Contract Laboratories

Laboratori Fundacio DAU,
Carrer de la Lietra C, 12-14,
Poligon Industrial de la Zona Franca
08040 Barcelona
SPAIN

ANNEX 5

Name(s) of Qualified Person(s)

Mr John W. Holloway (sterile and non-sterile medicinal products)

Ms Sandra Saliba Sammut (sterile and non-sterile medicinal products)

Mr Mark Ellul (non-sterile solid dosage form medicinal products only)

Mr Salvatore Venuto (sterile and non-sterile medicinal products)

Mr Daniel Cini (non-sterile medicinal products only)

Mr Chaitanya Sanjay Kanade (non-sterile medicinal products only)

Ms Jelena Konic (non-sterile medicinal products only)

Mr Srikanth Gattamaneni (non-sterile medicinal products only)

ANNEX 6

Name(s) of person(s) responsible for quality control

Mr Keith Frendo

Name(s) of person(s) responsible for production

Mr Dylan Drago

ANNEX 7

Date of Inspection on which authorisation was granted **17th-19th December 2026**

Scope of last inspection: **Routine General GMP Inspection**