

Subsidiary Permit 2 with introductory note

Environment Protection Act (CAP. 549);
Industrial Emissions (Framework) Regulations, S.L.549.76;
Industrial Emissions (Integrated Pollution Prevention and Control) Regulations,
S.L.549.77.

Installation **Medichem Manufacturing (Malta) Ltd & Combino Pharm (Malta) Ltd.**

Operator **Combino Pharm (Malta) Ltd
HF-61, Hal Far Industrial Estate
Hal Far BBG 3000**

Approved Documents: Permit number
IP 0002/05/E – framework document

Sub-permit numbers
IP 0002/05/Ei– Medichem Manufacturing (Malta) Ltd.
IP 0002/05/Eii – Combino Pharma (Malta) Ltd.

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Introductory note

The following Permit is issued under Regulation 7 of the Industrial Emissions (Framework) Regulations, 2013 (S.L.549.76 “the Industrial Emissions (Framework) Regulations”) to operate an installation carrying out activities covered by the description in Section 4.5 in Schedule 1 of the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L.549.77) to the extent authorised by the Permit, i.e.

“Production on an industrial scale by chemical or biological processing of pharmaceutical products including intermediates”.

Aspects of the operation of the installation which are not specifically regulated by conditions in the Permit may also be subject to the condition implied by Regulation 8 the Industrial Emissions (IPPC) Regulations, which require the Operator to use the best available techniques for preventing or, where that is not practicable, reducing emissions from the installation.

Techniques include both the technology used and the way in which the installation is designed, built, maintained, managed, operated and decommissioned.

In some sections of the Permit conditions require the Operator to use Best Available Techniques (BAT), in each of the aspects of the management of the installation, to prevent and where that is not practicable to reduce emissions. These conditions do not explain what is BAT.

A non-technical description of the installation is given in the Application, but the main features of the installation are summarized as follows:

- **Production of finished dosage forms**

Note that the Permit requires the submission of certain information to the Competent Authority In addition, the Competent Authority has the power to seek further information at any time under regulation 11 of the Industrial Emissions (Framework) Regulations, provided that it acts reasonably.

Other IPPC Permits relating to this installation

Permit holder	Permit Number	Date of Granting
<i>Not applicable</i>		

Superseded Licences/Authorisations/Consents relating to this installation

Holder	Reference Number	Date of Granting
<i>Combino Pharm (Malta) Ltd</i>	<i>EP0036/09/A</i>	<i>19 July 2010</i>
<i>Combino Pharm (Malta) Ltd</i>	<i>EP0036/09/B</i>	<i>6 May 2013</i>
<i>Combino Pharm (Malta) Ltd</i>	<i>EP0036/09/C</i>	<i>17 December 2014</i>
<i>Combino Pharm (Malta) Ltd</i>	<i>EP0102/20</i>	<i>24 July 2020</i>

Public Registers

This IPPC Permit and application is available to the public through the Competent Authority website in accordance with the requirements of the Industrial Emissions (IPPC) Regulations. Certain information may be withheld from the public where it is commercially confidential or contrary to national security. The applicant has made a request for certain information of a commercial nature to be withheld from the public. ERA has been supplied with all this information and has accepted the request of the applicant, because it was deemed to be commercially confidential.

Multiple Operator installations

As indicated in Regulation 6(3) of S.L. 549.76¹, a permit may regulate several parts of an installation operated by different Operators. The importance of integrating the operations of each technical unit stems from the definition of "installation" in the provisions of S.L. 549.76, where this is defined as "a stationary technical unit within which one or more activities listed in the regulations concerning integrated prevention and control or in the regulations concerning organic solvents are carried out, and any other directly associated activities on the same site which have a technical connection with these activities and which could have an effect on emissions and pollution".

In accordance to guidance provided by the Commission, an activity is considered to be a directly associated activity with a Schedule 1 activity if it shares common features, for example: it is part of the same industrial complex; it operates in the same or a related sector; or operates with some collective aspects such as site security.

This installation is therefore being regarded as a multi operator installation.

Functions of the permit

This **Subsidiary Permit 2** (IP0002/05/Eii) which addresses the operations carried out by Combino Pharm (Malta) Ltd, shall be regarded as part of the Permit IP0002/05/E which consists of three main parts structured as follows:

- **The Regulatory Framework Permit** addressing the obligation of all Operators and coordinating these obligations due to the nature of the facility as a multi-operator installation (IP 0002/05/E).
- **Subsidiary Permit 1** addressing the operation carried out by Medichem Manufacturing (Malta) Ltd. (IP 0002/05/Ei).
- **Subsidiary Permit 2** addressing the operations carried out by Combino Pharm (Malta) Ltd. (IP 0002/05/Eii).

Variations to the Permit

This Permit may be varied at any time in the future (by the Authority serving a Variation Notice on the Operator). If the Operator wants any of the Conditions of the Permit to be changed, a formal Application must be submitted to ERA. The Status Log within the Introductory Note to any such Variation Notice will include summary details of this Permit, variations issued up to that point in time and state whether a consolidated version of the Permit has been granted.

¹ S.L. 549.76 – Industrial Emissions (Framework) Regulations, 2013

Surrender of the Permit

Before this Permit can be wholly or partially surrendered, an Application to surrender the Permit has to be made to the Competent Authority by the Operator. For the application to be successful, the Operator must be able to demonstrate to the Authority that there is no pollution risk and that no further steps are required to return the site to a satisfactory state.

The Permit Holder shall notify the other Operators within the installation of any such intent so as to enable these entities to assess the impact of this proposal on their operations and on any obligations arising from either the Framework Permit or the Operator specific Subsidiary Permits.

Transfer of the Permit or part of the Permit

Upon the joint application of a Permit Holder and a proposed transferee, the Permit Holder may request to transfer an environment permit. The permit shall not be transferred from the Permit Holder without prior approval from the Authority. Upon the Authority's decision to transfer the permit to the transferee, all rights, obligations, liabilities shall subsist onto the transferee.

The Permit Holder shall notify the other Operators within the installation of any such intent so as to enable these entities to assess the impact of this proposal on their operations and on any obligations arising from either the Framework Permit or the Operator specific Subsidiary Permits.

Status Log

Detail	Date	Comment
EP application (EP0036/09/A)	11 September 2009	
Permit Granted	19 July 2010	
Variation Request	22 March 2013	Variation application Manufacturing cystostatic products
Permit Variation Issued	06 May 2013	
Renewal and variation determined	15 October 2009	
Application IP 0002/05/E for the relocation of QC lab from Medichem Manufacturing (Malta) Ltd. to Combino Pharm (Malta) Ltd. and the consideration of both operations as a multi- operator permit	5 March 2019	
Renewal application	17 July 2020	
Renewal determined	24 July 2020	Expires 24 January 2020
Application duly made	17 November 2020	
Public consultation	Commenced on 18 November 2020	Concluded on 2 December 2020
Permit Determined	15 th January 2021	

End of Introductory Note

Conditions

1 General

This permit shall be read in conjunction with the Regulatory framework Permit and the Subsidiary Permits issued to Medichem Manufacturing (Malta) Ltd. and Combino Pharm (Malta) Ltd., together with the Regulatory Framework Permit which together comprise permit IP 0002/05/E.

Environmental Permit EP 102/20 is hereby superseded.

1.1 Permitted Activities

1.1.1 The Operator is authorised to carry out the activities and the associated activities specified in Table 1.1.1.

Table 1.1.1		
Activity	Description of specified activity	Limits of specified activity
Manufacture of pharmaceutical preparations	Manufacture of pharmaceutical products (non-sterile solid dosage forms: tablets and capsules)	From receipt of raw materials and associated chemicals to dispatch of finished product (including packing and testing). Includes the manufacture of cytostatic/cytotoxic products. Does not include the preparation of any APIs (including intermediates) using a chemical/biological reaction. Does not include the manufacture of hormones or injectables.
Associated activity of utilities	LPG boiler to produce steam and hot water. Emergency diesel generator to produce energy. Reverse osmosis for water purification.	From receipt of fuel to delivery of utility. From receipt of fuel to delivery of energy. From receipt of water to delivery of utility.
Associated activity of storage, treatment and disposal/recycling of	Handling, storage, treatment and containment of wastes from	From generation of waste to disposal or recycling (including recovery) offsite at

waste materials	installation prior to disposal.	permitted facilities.
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1.2 Site

- 1.2.1 The activities authorised under condition 1.1.1 shall not extend beyond the Site, as shown on the Site Map in Schedule 2 to this Permit.
- 1.2.2 Site security systems shall be implemented at all times during the subsistence of this Permit, the objective of which shall be to prevent access which is not authorised either by the Permit Holder or under legal powers of entry. These shall be installed, operated and maintained, and shall be fully documented and recorded.

1.3 Improvement Programme

- 1.3.1 The Permit Holder shall complete the improvements specified in Table 1.3.1 by the date specified in that table, and shall send written notification of the date of completion of each requirement to the Authority on ced.facilities@era.org.mt within 10 working days of the completion of each such requirement.

Table 1.3.1: Improvement programme		
Reference	Requirement	Date
1	Submission of a noise monitoring method statement in line with Schedule 2 of the Framework permit Implementation of a noise monitoring exercise and submission of the report.	Within three months from the granting of the permit Within one year from the granting of the permit
2	Submission of an addendum to the land and groundwater risk assessment for the consideration of Combino Pharm Ltd. site.	Within one year from the granting of the permit
3	Submission of the monitoring proposal for a one-time air emission monitoring exercise from the fume hood exhaust vents (PS4-PS6)	By 31 December 2021

1.4 Pre-Operational Conditions

- 1.4.1 There are no pre-operational conditions.

1.5 General Conditions

- 1.5.1 The permit is granted against a Bank Guarantee of € 11,850 which shall be renewed annually. This guarantee will have to be maintained throughout the validity of the permit. Following renewal and/or variations to this permit, the Authority may require amendments to the Bank Guarantee.
- 1.5.2 The Bank Guarantee shall remain in place for the duration of validity of this

permit and shall only be released upon confirmation of full compliance with the permit conditions by the Authority.

- 1.5.3 The Authority may take part or all of the bank guarantee if the Permit Holder fails to take the necessary action, or fails to fulfil his legal obligations under the Act or its subsidiary legislation thereof, in cases of non-compliance with these permit conditions, or in cases where environmental integrity is threatened. This bank guarantee is without prejudice to any environmental liabilities incurred by the Permit Holder through failure to adhere with permit conditions or any other works/activity carried out on site. Should the Authority forfeit the Bank Guarantee either in part or in full, the permit holder shall ensure that this is replenished without undue delay, in any case not exceeding 2 months from the date of forfeiture.
- 1.5.4 In cases where the bank guarantee does not cover the expenses incurred by the Authority to take any remedial action on the Permit Holder's behalf, the Permit Holder is to financially reimburse the Authority of all the expenses incurred within.
- 1.5.5 The operator shall submit a fixed annual fee of €1500 and a variable addition reflecting ERA's cost for inspections. The latter variable component depends on the actual number of site inspections, which is determined by the performance of the operator. The total annual contribution has to be paid annually before the anniversary of the date of issue of this permit.
- 1.5.6 Without prejudice to condition 1.5.3 the Authority may take any action deemed necessary including but not limited to the suspension of any activity/operation until investigations are concluded.

2 Operating Conditions

2.1 Emissions to Air

- 2.1.1 The Operator shall prevent or where that is not practicable reduce fugitive emissions of substances to air from the Permitted Installation.
- 2.1.2 Emissions to air shall only arise from the emission points specified in Table 2.1.2, as described Schedule 3.

Table 2.1.2 : Emission points to air	
Emission point references (Schedule 3)	Source
PS1	Boiler
PS2	Generator
PS3a	HVAC production process room
PS3b	HVAC production room
PS3c	HVAC production room
PS3d	HVAC packaging room
PS3e	Fluid bed drier & coater
PS3f	Fluid bed drier emergency stack
PS3g	Coater
PS4	Fumehood vent
PS5	Fumehood vent
PS6	Fumehood vent

- 2.1.3 The Permit Holder(s) shall submit certification for PS1 & PS2, by an independent warranted engineer showing that the boilers are in good working condition every four years. The certifications shall be submitted as part of the

Annual Environmental Report (AER).

- 2.1.4 Only LPG shall be utilised as a source of fuel for the boilers. The co-incineration of any material or additional fuel including engine or other waste oil is strictly prohibited. Any change in fuel type shall require the notification and approval of the Authority prior to commencement of its utilisation.

Volatile Organic Compounds

- 2.1.5 In the event that the VOC solvent consumption threshold exceeds 50 tonnes/year as per Activity 20 in Schedule II of S.L.549.79 (the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations), the operator is to notify the Authority, and the provisions of S.L.549.79 shall apply.
- 2.1.6 The Permit Holder shall inform the Authority in advance should there be an intention to use any VOC solvents as per S.L. 549.79 which because of their content of volatile organic compounds, are classified as carcinogens, mutagens, or toxic to reproduction, and are assigned or need to carry the hazard statements H340, H341, H350, H350i, H351, H360D or H360F. In this case, the Authority may set emission limits for these substances and monitoring requirements.

Emergency Considerations

- 2.1.7 Operation of the fluid bed drier emergency stack may only take place if the fluid bed drier is in an operational state that might otherwise cause danger to human beings or severe damage to the plant, e.g. acute danger of explosion. In the case of installation of new fluid bed driers, the operator shall endeavour to install and utilise alternative techniques, which in the case of an emergency, do not require use of an emergency stack.
- 2.1.8 The operator shall take all possible precautions (including maintenance, risk assessment, use of suitable materials in relation to the limitations of the fluid bed drier, etc.) to ensure that the likelihood of emergency stack use is minimised.
- 2.1.9 In case of emergency stack operation, the process occurring in the fluid bed drier must be stopped immediately and automatically. The duration of emergency stack operation must be reduced to the utmost minimum.
- 2.1.10 The Permit Holder shall maintain an emergency procedure that is specific to the use of the fluid bed drier emergency stack. The procedure shall include actions to be taken to minimise the release, and immediate notification of ERA, the Civil Protection Department and neighbours in case of an incident.
- 2.1.11 In the event of emergency stack operation, a report shall be submitted to ERA within two working days describing:
- a) the cause of emergency stack operation;
 - b) the duration of emergency stack operation;
 - c) the quantity of emissions resulting from emergency stack operation;
 - d) measures being implemented by the operator to minimise the probability of recurrence of such an incident.
- 2.1.12 The emergency stack vent shall be directed in such a way as to minimise impact to the surroundings in case of emissions.

2.2 Effluent discharges

2.2.1 The Operator is allowed to discharge process water to the wastewater treatment plant and second reservoir of Medichem Manufacturing (Malta) Ltd (of HF-61, Hal Far Industrial Estate, Malta), provided that:

- a) Wastewaters from Combino Pharm are treated in Medichem's on-site wastewater treatment plant prior to discharge, except where the wastewaters from Combino Pharm are in conformity with the limits set in the Water Services Corporation Sewer Discharge Permit for Medichem and do not require treatment prior to discharge.
- b) Wastewaters from Combino Pharm do not result in any exceedance of the limits set in the Water Services Corporation Sewer Discharge Permit for Medichem.

2.3 Noise and Vibration

2.3.1 A noise monitoring exercise shall be carried out within the timeframe specified in table 1.3.1, as in accordance with Schedule 2 of the Framework permit.

2.3.2 The level of noise emitted from the installation at all operational times shall not exceed the background noise level by more than 5dB.

3 Interpretation

3.1 The interpretation and relevant expressions as defined in Section 6 of the Framework Permit (IP0002/5/E) shall also apply to this Subsidiary Permit.

3.2 Where any condition of this Permit refers to the whole or parts of different documents, in the event of any conflict between the wording of such documents, the wording of the Framework Permit shall prevail to the extent of such conflict.

Schedule 1
Annual Environmental Report

Important note

By this submission, you confirm that you give your explicit consent for the entire contents of this Annual Environment Report to be made available on the Authority's public website.

S1.1 Introduction

Environmental Permit Number	
Name and locality of Site	
Brief description of activities at the site	
Reporting Year (Calendar Year: 1 January to 31 December)	

S1.2 Environment Management System

Please attach a supporting document with the following:

1. A summary of the installation's Environmental Policy containing the installation's environmental objectives and targets;
2. Summary of the Environmental Management Programme report (for the reporting year);
3. Summary of the Environmental Management Programme proposal (for the following year);
4. European Pollutant Release and Transfer Register Report (as per Condition 4.3 of the Framework Permit).

Tick (✓)

S1.3 Process Data**S1.3.1 Annual Summary**

	Units	Previous reporting year	Current reporting year
Quantity of product	tonnes		
Total Annual Energy Consumption (from electricity and other sources)	MWh		
Energy consumption per unit product	MWh/tonne of product		
Annual water consumption	m ³		
Water consumption per unit product	m ³ /tonne of product		
Annual quantity of waste produced	tonnes		
Waste produced per unit product	tonne waste/tonne product		

S1.3.2 Fuel Consumption Data

Equipment ¹	Fuel type	Sulphur Content of Fuel ²	Fuel Consumption	Units
Boiler	LPG			tonnes
	Diesel			tonnes
Generator	Diesel			

S1.3.3 List of Raw Materials

Raw Material	Risk phrase	Annual Quantity Used (kg)

S1.3.4 Data on Ozone depleting substances and Fluorinated greenhouse gases

Table 1: registration of equipment

Equipment code	Type of equipment	Use	Charge		Type of substance
			Kg	CO ₂ (eq)	
EQ 1					
EQ 2					
EQ 3					
EQ 4					
Continue as required					

Table 2: Maintenance Schedule³

Data Submitted for scheduled inspection ⁴	Equipment Code							
	EQ 1	EQ 2	EQ 3	EQ 4	EQ 5	EQ 6	EQ 7	Continue as required
Date of inspection								
All amounts of leakages detected (in Kg/ CO ₂ equiv ⁵)								
Actions taken to eliminate such leakages								
Quantity and nature								

¹ E.g. Boiler, generator, vehicles, etc.

² Specify units (e.g. as percentage, or mg/kg)

³ (a) for equipment that contains fluorinated greenhouse gases in quantities of 5 tonnes of CO₂ equivalent or more, but of less than 50 tonnes of CO₂ equivalent: at least every 12 months; or where a leakage detection system is installed, at least every 24 months; (b) for equipment that contains fluorinated greenhouse gases in quantities of 50 tonnes of CO₂ equivalent or more, but of less than 500 tonnes of CO₂ equivalent: at least every six months or, where a leakage detection system is installed, at least every 12 months; (c) for equipment that contains fluorinated greenhouse gases in quantities of 500 tonnes of CO₂ equivalent or more: at least every three months or, where a leakage detection system is installed, at least every six months.

⁴ Table to be repeated for every scheduled inspection as per 'footnote 1' above.

⁵ Carbon Dioxide equivalent – use Annex 1 and Annex IV of EC517/2014 for calculation.

of the substances involved								
Serial number of the personnel involved								
Quantities added ¹ and/or recovered (in Kg/ CO ₂ equiv).								

S1.4 Monitoring Data

S1.4.1 HEPA Filter Integrity Monitoring

Date of Inspection	Differential Pressure							Continue as required
	HF1	HF2	HF3	HF4	HF5	HF6	HF7	
Week 1								
Week 2								
Week 3								
Continue as required								

Additional documentation to be submitted:

Efficiency certification	Tick (✓)
HF1	
HF2	
HF3	
HF4	
HF5	
Continue as required	

¹ The quantities of added fluorinated greenhouse gases are from recycled or reclaimed stocks, please include the name and address of the recycling or reclamation facility and, where applicable, the certificate number

S1.5 Off-site transfers of waste

Date of transfer	EWC Code ¹	Description of waste	Quantity of waste (in kg)	Treatment applied before transfer	Mode of transport	Names of agent & transporter of waste (GBR Number)	Ultimate destination (address) of waste	Consignment note number/ (Trans frontier Shipment of waste) reference number ²	Name of person responsible for ultimate disposal/recovery	Final destination	Details of Recovery (if applicable)

¹ European Waste Catalogue Code (Reference: Commission Decision 2000/532/EC: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0955&from=EN>)

² For hazardous waste only. If waste is not hazardous, please write "n/a".

S1.6 Testing of site containment and drainage systems, and fuel transfer system

	Number on site	Date of last test	Certification submitted (Tick ✓)	Testing due on (date)
Catchment pits				
Bunds				
Pipes				
Pumps				
Valves				
Flanges				
Others: (specify)				

Additional documentation to be submitted if test was carried out during previous reporting year:

Certification by warranted architect or engineer Tick (✓)

S1.7 Environmental Incidents and Complaints

S1.7.1 Environmental Non-Compliance Incidents during Reporting Year

Date of incident	Brief description of incident	Cause	Corrective action

Total number of non-compliance incidents for previous year:	
Total number of non-compliance incidents for current reporting year:	

S1.7.2 Complaints made by the public to Medichem Manufacturing (Malta) Ltd.

Date of complaint	Description of complaint	Actions taken

Total number of complaints for previous year:	
Total number of complaints for current reporting year:	

S1.8 Submission of Certifications and Documentation

Submission	Tick (✓)
Noise monitoring report	<input type="checkbox"/>
Good-working order certificate for generator and boiler prior to the renewal of the permit	<input type="checkbox"/>
Engineers certification of process pipes, valves and flanges prior to the renewal of the permit	<input type="checkbox"/>

Applicant's declaration

I declare that, to the best of my knowledge, all the above information is correct and substantiated.

.....
Name
(in block letters)

.....
ID Card Number

.....
on behalf of / in my own name
(in block letters)

.....
Signature

.....
Date

Schedule 2 Site Map

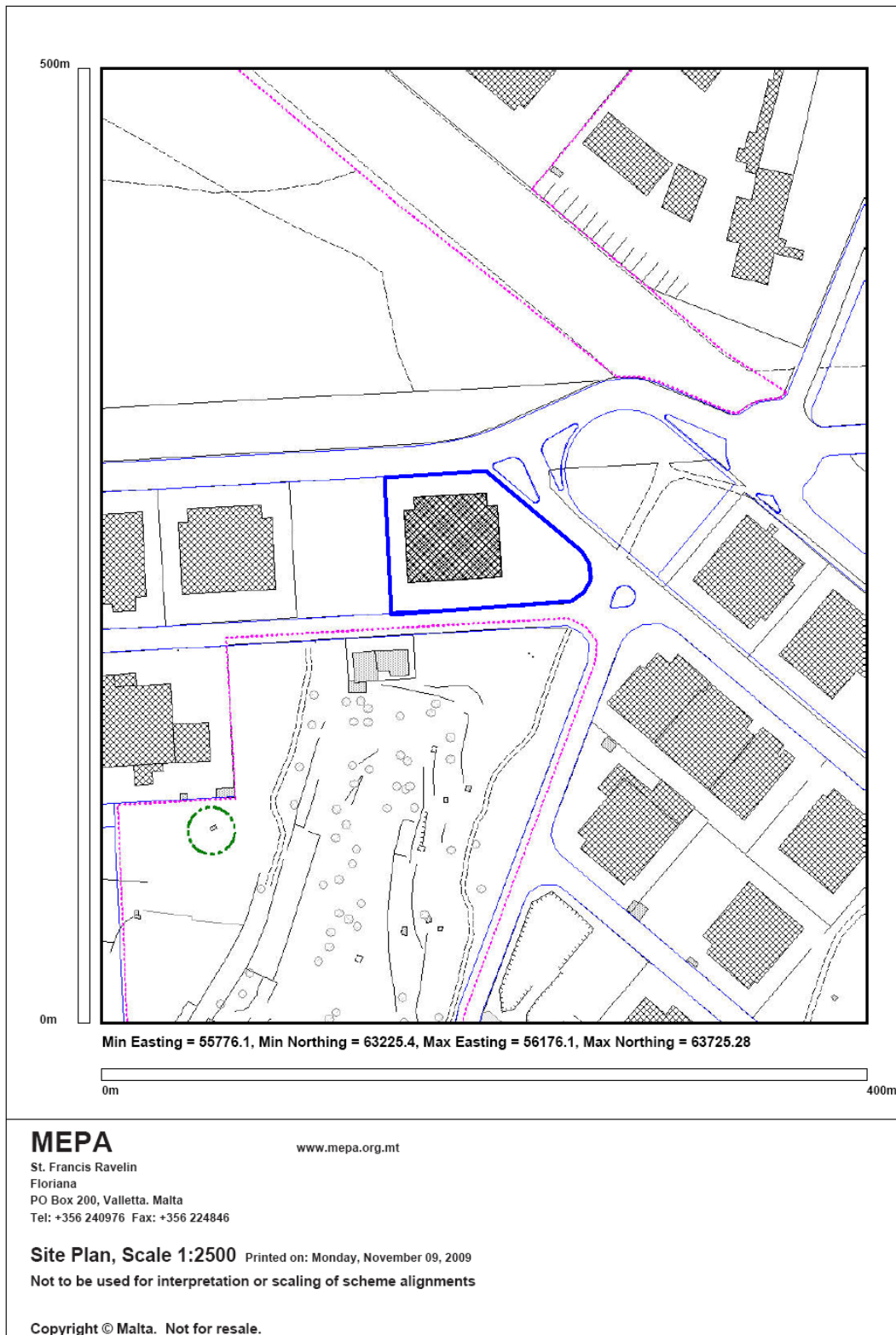
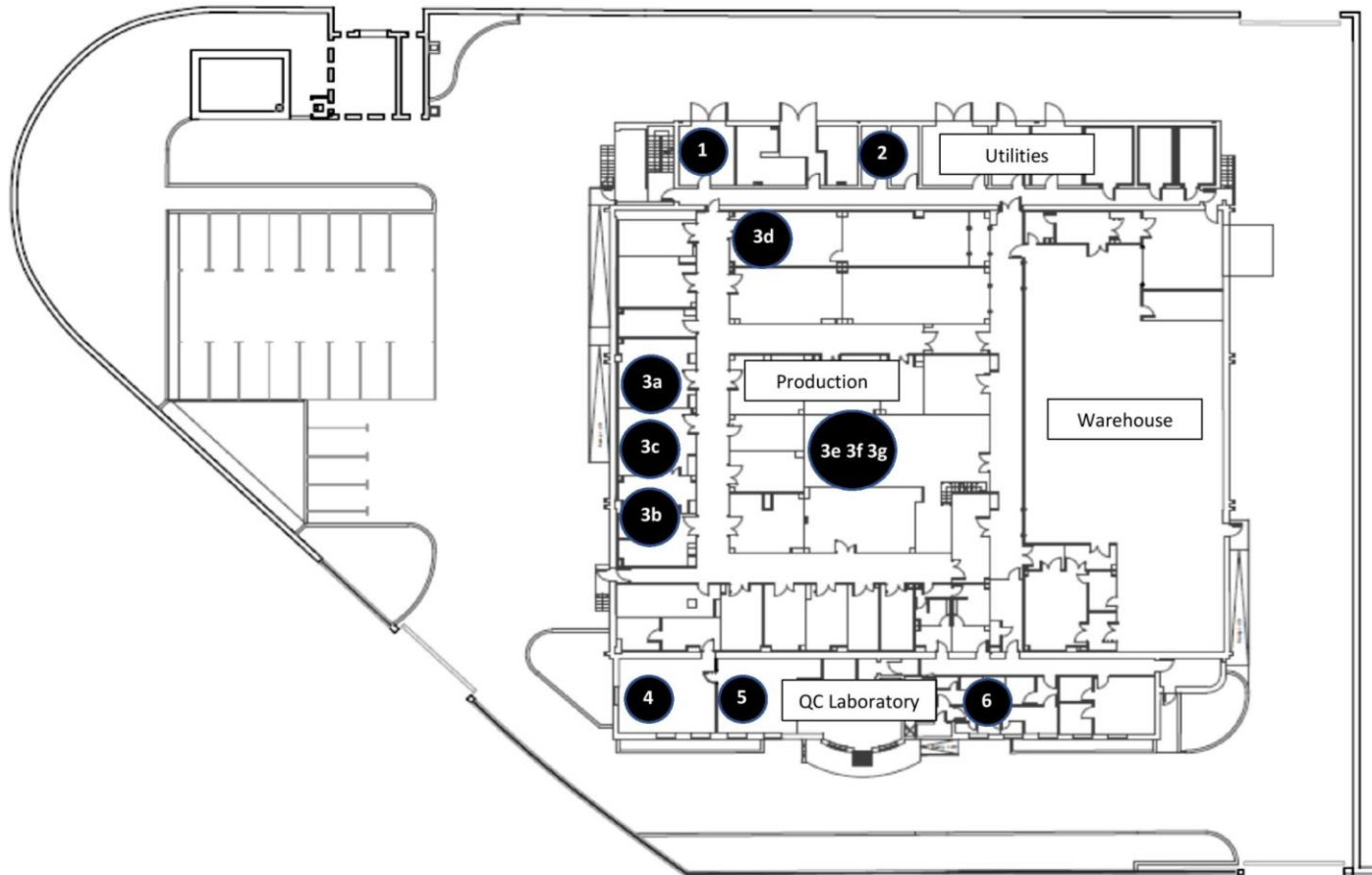


Fig. S2.1: Site of installation, showing extent of area authorised for activity (outlined in bold blue).

**Schedule 3
Site Layout Plan**



END OF PERMIT