GOVERNMENT OF MALTA
MINISTRY FOR HEALTH AND ACTIVE AGEING

LICENCE CERTIFICATE

This is to certify that, in terms of the Health Act (Cap 528), the Licensing of Private Medical Diagnostic Laboratories Regulations (S.L. 458.25) and other applicable laws and regulations, the Superintendence of Public Health has granted **Dr Manuele Biazzo** a licence to operate a **Medical Diagnostic Laboratory** at the premises which details appear below.

The BioArte Ltd
Malta Life Science Park
Triq San Ġiljan
San Ġwann

This licence is issued with effect from the 1st January 2026, subject to the provisions mentioned above as well as to the specific conditions listed overleaf.

This certificate is valid until the 31st December 2026.

Prof. Charmaine Gauci
Superintendent of Public Health

On behalf of

Hon Jo Etienne Abela
Minister for Health and Active Ageing

Office of the Superintendent of Public Health
Outpatients Dept. Level 1, St. Luke's Hospital Gwardamangia
Tel: 356 2595 3302/3 email: sph.health@gov.mt

CONDITIONS OF LICENCE - 2026 - MEDICAL DIAGNOSTIC LABORATORIES

This licence is issued in terms of the Health Act (Cap 528), the Licensing of Private Medical Diagnostic Laboratories Regulations (S.L.458.25) and other applicable laws and regulations, subject to the following terms and conditions: -

General

1. The facility shall, at all times, be kept in conformity with sanitary laws and regulations, clean and in a good state of repair; no structural alterations are to be carried out without prior approval from the Superintendent of Public Health. The premises shall have a separate entrance from any other businesses or private residences.
2. The facility should comply with any relevant standards issued by the Healthcare Standards Directorate within the Health Regulation Department.
3. The licensee shall ensure that there are adequately trained personnel, facilities, and resources to support the provision of professional healthcare services to patients and which allow for their individual needs.
4. The Superintendent of Public Health reserves the right to carry out inspections of the premises at any time it is deemed fit.
5. The facility and grounds shall comply with the requirements of the Commission for the Rights of Persons with Disability. 'Access for all design guidelines'.
6. The licence certificate shall be kept affixed in a conspicuous place which is readily accessible to the service users and to the public.
7. The facility shall have adequate lighting, emergency lighting and ventilation. There should also be control of temperature in the facility.
8. There shall be a sufficient number of toilets, hand hygiene facilities and bathrooms which are commensurate with the facility's size and case mix. These shall be kept clean, in a good state of repair and adequately furnished with the necessary toiletries.
9. The licensee shall ensure free and unencumbered access in case of emergency.
10. The licensee shall ensure sufficient space, that staff, equipment, and facilities are available to perform the required work in accordance with relevant standards of quality and safety.

Safety

1. Fire-fighting appliances, facilities and training and an adequate evacuation plan shall be such as may be determined from time to time by the Competent Authority.
2. The licensee shall take all necessary precautions to ensure the safety of all staff on the premises. Moreover s/he shall provide adequate means of protection against occupational hazards and ensure that all staff are appropriately trained and make appropriate use of the protective equipment provided.
3. The licensee is responsible for ensuring that no contaminated or potentially infected material is deposited for collection by refuse collectors. Such articles are to be placed in appropriate puncture-proof containers and disposed of in line with current policy and through a registered waste collector.
4. Smoking areas shall be maintained in conformity with National legislation.

Staff

1. The Health Regulation Department (Healthcare Standards Directorate) is to be kept informed of the name, age, address, and qualifications of all personnel employed by the licensee and of any new personnel employed thereafter. (Registration number-where applicable).
2. Each patient must have a comprehensive treatment record, which must be kept securely in accordance with the requirements of the Data Protection Act. (Cap 586).
3. The licensee shall ensure that the facility has effective systems in place to support quality assurance and good governance.
4. All medical laboratory tests shall be authorised by the request of a caring physician, and all results shall be issued and communicated to clients under the professional direction, supervision, and responsibility of the caring physician.
5. All tests shall be carried out by staff who are suitably qualified and registered as Medical Laboratory Scientists with the Council of Professions Complementary to Medicine. All persons employed at the Laboratory shall be of good conduct. All staff shall register their attendance at the Laboratory, including the date/time of entry and the date/time of leaving the Laboratory. Such records shall be retained for a period of at least two years from the date of the last entry register.

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Laboratory Policies

1. There shall be written policies and procedures for:
   a. Laboratory quality control, both for internal and external procedures
   b. Preventive maintenance and/or Service agreements on instruments
   c. Laboratory safety.
2. The licensee is responsible for ensuring that all policies are implemented and adhered to by employees, and that all staff are provided with adequate training to ensure that the required standards of Quality and Safety are maintained at all times.
3. All deviations or variations from approved policy shall be managed in accordance with the provisions of the Quality Management System.
4. Quality Control Records (external and internal), including servicing and preventative maintenance of equipment, shall be kept for at least 10 years.

Results Register

1. All tests carried out at the Laboratory shall be registered together with the following information:
   a. Patient's name, ID number, sex, address, and date of birth
   b. Referring Clinician's name and medical registration number
   c. The date when requested and their results
   d. The test(s) requested and their results
   e. The Professional who carried out the test(s).
2. Such records shall be retained at least for the minimum period stipulated according to the regulations in force (Reg 9 of S.L 458.25) and made readily available for verification during inspection by HCSD officials.

Notification of diseases

1. The licensee or a representative shall inform the Superintendence of Public Health forthwith through written communication of:
   - Any infectious disease notifiable under the Public Health Act (Cap 465)
   - Any malignant disease diagnosed at the Laboratory in accordance with Reg 10 of S.L 458.25

The information submitted shall include the patient's name and ID number, and the referring Clinician's name and medical registration number.

Register

The Superintendent of Public Health has the right to publish a list of names of licensed Medical Diagnostic Laboratories on the Directorate's website.

Conditions

1. The Superintendent of Public Health reserves the right to recommend withdrawal of any licence and/or take any further action deemed necessary to safeguard public health and patient safety in the case of failure to observe the required standards of care or adhere to any licence condition or regulation.
2. It is the responsibility of the licensee to notify the Superintendent of Public Health if, at any time, and for whatever reason, any divergence from the terms and conditions of this licence arises, and keep the authority informed of any incidents which may impact upon patient safety and public health.
3. The introduction of any new service, facility, or equipment other than that covered by virtue of this licence requires the prior permission of the Superintendent of Public Health, which may necessitate on-site inspection and/or supporting documentation before being made available to patients.

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