

*This is to Certify that the Quality Management Systems for Medical Devices of*



## **Biosphere Biological Technics (PGT)**

Kassas Gremda Km 9 Chihia 3041, Sfax, Tunisia

has been independently assessed and registered by B-ADVANCY  
as conforming to the requirements of

### **ISO 13485:2016**

**For the following Scope:**

“Manufacture and Distribution of Medical Devices and in vitro Devices for Single Use:

- MD: Vaginal Speculum, Electrode for ECG, Swabs and Laboratory Consumables
- IVD: Single-use Containers for the Collection of Human Venous Blood and non-blood Samples of Human Origin.”

**Certificate No. : 2308120TN**

Date of initial registration : 15<sup>th</sup> Aug 2023

Date of this certificate : 14<sup>th</sup> Aug 2023

Date of expiry : 13<sup>th</sup> Aug 2026

1<sup>st</sup> Surveillance audit on or before : 14<sup>th</sup> July 2024

2<sup>nd</sup> Surveillance audit on or before : 14<sup>th</sup> July 2025

Validity of the certificate is subject to completion of surveillance audit on or before the due date. In case the surveillance audit is not allowed to be conducted, this certificate shall be suspended/subject to withdrawal.



  
Director



Certificate can be verified on [www.b-advancy.com](http://www.b-advancy.com) and Accreditation Board's [www.asib.co.uk](http://www.asib.co.uk) website

This Certificate is the property of B-ADVANCY Certification UK Ltd. and shall be returned immediately when demanded.

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