

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Bionobis
7 Rue Nicolas Copernic
Guyancourt
78280
France

Holds Certificate Number:

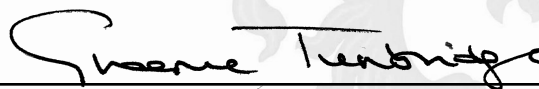
MD 739925

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Development, Manufacture and Distribution of In-Vitro Diagnostic Reagents and Software utilizing Next Generation Sequencing technology for HLA Typing.

Importation and Distribution of IVD Reagents, Instrument, Software and Consumables.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-05-02

Latest Revision Date: 2025-05-02

Effective Date: 2025-05-02

Expiry Date: 2028-05-01

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