

Certificate of Registration

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

This is to certify that:

Biofortuna Limited
2 Tenth Avenue
Deeside Industrial Park
Deeside
CH5 2UA
United Kingdom

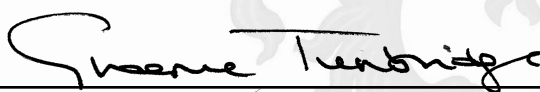
Holds Certificate Number:

MD 731514

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 validation of in vitro diagnostic reagents and kits for genotyping and phenotyping assays.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-12-15

Latest Revision Date: 2024-09-25

Effective Date: 2024-11-13

Expiry Date: 2027-11-12

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