

# 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:

Contract design and manufacture of nucleic acid-based and immunodiagnostic assays and reagents for in vitro diagnostic genotyping and phenotyping assays. Contract design, development and manufacture of in vitro diagnostic lyophilised assays and reagents.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-12-15

Latest Revision Date: 2022-03-16

Effective Date: 2021-11-13

Expiry Date: 2024-11-12



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