

CERTIFICATE

Number: 22-MED-0301_001 003

The management system of:

Fortress Diagnostics Ltd

Unit 9A,
The Technology Park,
Belfast Road,
Co, Antrim
BT41 1QS

including the implementation meets the requirements of the standard:

ISO 13485:2016

Scope:

Design, manufacturing and distribution of In Vitro Diagnostic medical device kits, reagents, and controls including Immunoassay, Clinical Chemistry, Point of Care, Haemostasis and Serology. Distribution of instrumentation for Clinical Chemistry, Point of Care, Blood Grouping, Haemostasis and Serology and the distribution of blood grouping in vitro diagnostic medical device kits

Certificate expiry date: 28 February 2025
Certificate effective date: 12 May 2022
Certified since: 21 September 2021

Certificate ID#M – 67/2/2021 expired on 28 February 2022. The Renewal Audit was carried out on date: 16-02-2022. The certificate 22-MED-0301_001 has been renewed on date: 14-04-2022. Revision 002 and 003 of Certificate ID #0301 issued as a result of a notice of change relating to scope wording clarification.

DEKRA Certification UK Ltd



Managing Director



Certification Manager

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