

CERTIFICATE

Number: 22-MED-0301_001 005

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: 15 December 2023
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 February 2022. The certificate 22-MED-0301_001 has been renewed on date: 14 February 2022. Revision 002 and 003 of Certificate ID#0301 issued as a result of a notice of change relating to scope wording clarification. Revision 004 of Certificate ID #0301 issued as a result of a correction of UKAS symbol and removal of MD signature on certificate template. Revision 005 of Certificate ID #0301 issued 15 December 2023 as a result of amendment to symbol and change in certificate template.

DEKRA Certification UK Ltd



Managing Director
Christopher J Blue



Certification Manager
Abul Kashem

© Integral publication of this certificate and adjoining reports is allowed



DEKRA Certification UK Ltd
Stokenchurch House, Oxford Road, Stokenchurch, Bucks, ENGLAND, HP14 3SX
+44 330 9120 368 certification.uk@dekra.com Company Registration Number 13129030

3966:1