



EC Declaration of Conformity (Directive 98/79/EC)

Manufacturer: Fortress Diagnostics Limited, Unit 9A, The Technology Park, Belfast Road, Antrim, Northern Ireland, BT41 1QS, United Kingdom

Manufacturer Identification: IVD GB/000277

Competent Authority: Medicines and Healthcare Products Regulatory Agency (MHRA), Competent Authority GB/CAO1

Product Details: See MHRA Letters and list attached

Classification: IVD, Non Annex II, Self-Declaration

Conformity Assessment Route: Annex III IVDD

We hereby declare that the devices named in the EC Declaration of Conformity List (see list-attached) comply with the requirements of DIRECTIVE 98/79/EC on in vitro diagnostic devices and associated instrumentation.

Fortress Diagnostics Limited has a Quality Management System in place based on ISO 13485:2016.

Standards Applied: EN ISO 13485:2016.



QUALITY MANAGEMENT SYSTEM

ISO 13485 CERTIFIED COMPANY

Signed:

Date: 15 Feb 2022

Name: **Dr Morteza Afrasiabi**

Position: **Managing Director**

Place: **Fortress Diagnostics Limited**