EC DECLARATION OF CONFORMITY

Issued Date: 14th April, 2020

The Manufacturer, Edinburgh Genetics Limited, registered in Scotland at 64a Cumberland Street, Edinburgh, United Kingdom EH3 6RE, declares that the below products have been CE marked according to the requirements in the In Vitro Diagnostic Medical Device Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998.

It is declared that:

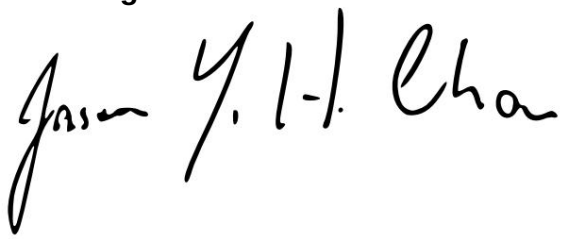
1. The below product(s) have been correctly classified as General IVDs.
2. The products meet the essential requirements in Annex 1 of the Directive.
3. The relevant technical documentation has been prepared which details the manufacturing process and shows the principles of quality assurance have been followed.
4. The CE mark has been affixed to the product labels and IFUs where appropriate.
5. Prior to marketing the products, the Manufacturer has registered these products with a Competent Authority, which is the Medicines and Healthcare products Regulatory Agency in the United Kingdom.

Product(s)

Edinburgh Genetics ActivXpress+ COVID-19 IgG/IgM Immunoassay Complete Testing Kit

For and on behalf of

Edinburgh Genetics Limited



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