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

Manufacturer Omega Diagnostics Ltd., Omega House, Hillfoots Business Village, Alva, Clackmannanshire, FK12 5DQ, Scotland, United Kingdom

Manufacturer Identification Code: 0000000024

Competent Authority: Medicines and Healthcare Products Regulatory Agency, Competent Authority GB / CA 01

European Authorised Representative: EMERGO EUROPE, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands

Product Details: See EC Declaration of Conformity List (attached)

Classification: General IVD (others)

Conformity Assessment Route: Annex III IVDD

We hereby declare the devices named in the EC Declaration of Conformity List (see attached) comply with the requirements of DIRECTIVE 98/79/EC, on in vitro diagnostic medical devices.

Standards Applied: EN ISO 9001:2015, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN 13612:2002 EN 23640:2015 and EN 13641:2002.

Signed:

Name: Angela Robertson
Position: Group Regulatory Affairs Director
Place: Omega Diagnostics Ltd., Omega House, Hillfoots Business Village, Alva, Clackmannanshire, FK12 5DQ, Scotland, United Kingdom
Date: 19 March 2021

EC Declaration of Conformity List

GMDN Classification	Description	Product Product Code - Test Size
63165	CD4 cell marker IVD, kit, immunochromatographic test (ICT), rapid	VISITECT® CD4 Rapid Test OD296 - 25 Tests OD296N - 25 Tests OD296R - 25 Tests VISITECT® CD4 Advanced Disease Rapid Test OD376 - 25 Tests OD376N – 25 Tests
64956	SARS-CoV-2 immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, immunochromatographic test (ICT), rapid	VISITECT® COVID-19 IgM/IgA/IgG OD910 - 25 Tests
64787	SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	VISITECT® COVID-19 Antigen OD930 – 25 Tests