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

Manufacturer Omega Dx (Asia) Pvt. Ltd, International Biotech Park, TCG 4th Floor, BTS II Bldg, Chrysalis Enclave, Block 2, Phase II, Hinjewadi, Pune – 411057, Maharashtra- India.

Manufacturer/ Authorised representative Identification Code: IVD000936

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

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 13485:2012, 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: 08 March 2018

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Parasitology (Microbiology) (14 05) Detection and Identification (Parasitology) (14 05 02)		
14 05 02 02 00	Plasmodium falciparum	VISITECT® Malaria Pf OD336 – 25 Tests ODX336 – 25 Tests
14 05 02 02 00		VISITECT® Malaria Pf/Pv OD216 – 25 Tests ODX216 – 25 Tests
14 05 02 02 00		VISITECT® Malaria Pf/PAN OD326 – 25 Tests ODX326 – 25 Tests
Pregnancy Testing Hormones / Proteins (12 05 02)		
12 05 02 05 00	Human Chorionic Gonadotropin Total (hCG)	VISITECT® Pregnancy OD036 – 25 Tests OD056 – 100 Tests