

EC DECLARATION OF CONFORMITY



We,

BEIJING WANTAI BIOLOGICAL PHARMACY ENTERPRISE CO.,LTD, located at No.
31 Kexueyuan Road, Changping District, Beijing, 102206, P.R. of China

self-declare under our sole responsibility that the products

Product Name	Product Code	GMDN Code	Competent Authority Registration Number
HAV- IgM ELISA	WA-1196	48281	BE-CA02-306-16
Anti-TP (Syphilis) ELISA	WT-5296	30687	BE-CA02-315-08
TB-IGRA	WT-1196	60744	BE-CA02-310-16
HEV- IgM ELISA	WE-7196	30758	BE-CA02-060-08
HEV- IgG ELISA	WE-7296	30757	BE-CA02-314-08
HEV- Ag ELISA ^{Plus}	WE-7596	30753	BE-CA02-042-14
Rapid Test for IgM Antibody to Hepatitis A Virus (Colloidal Gold Device)	WJ-1010, WJ-1050	48282	BE-CA02-307-16
Rotavirus Group A Diagnostic Kit (Colloidal Gold Device)	WJ-1910, WJ-1950	50245	BE-CA02-308-16
Rapid Test for Antibody to Syphilis (Colloidal Gold Device)	WJ-1610, 1650,1610E, 1650E	30687	BE-CA02-309-16
HEV- IgM RAPID TEST	WJ-1510	30758	BE-CA02-043-14
Wantai SARS-CoV-2 Ab ELISA	WS-1096	/	

Classification under IVDD: not listed in Annex II

meet(s) the provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices.

The following (harmonized) standards have been applied: EN ISO 18113-1:2011, EN ISO18113-2:2011, EN ISO 15223-1:2012, EN 13612: 2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2012, EN ISO 13485:2016 .

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe.

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Ms. Zhao Lingzhi (QA Manager)
Beijing, February 26, 2020



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