EC DECLARATION OF CONFORMITY

We, **Beijing Wantai Biological Pharmacy Enterprise Co., Ltd which are located at No. 31 Kexueyuan Road, Changping District, Beijing, 102206, P.R. of China**

declare under our sole responsibility that the product(s)

Type(s)	Devices	Catalog No.	GMDN Code	Nodified Body's Certificate no.
AiD™ HIV 1+2 Ag/Ab ELISA^{Plus}	Diagnostic Kit for Antibody and Antigen to Human Immunodeficiency Virus (ELISA)	WI-44S96 WI-44S480	48445	EC Certificate IVDD 020 077 0112 rev.1 EC Certificate IVDD 020 077 0113 rev.1
AiD™ anti-HIV 1+2 ELISA	Diagnostic Kit for Antibody to Human Immunodeficiency Virus (ELISA)	WI-4396 WI-43480	48451	EC Certificate IVDD 20 076 0122 EC Certificate IVDD 20 076 0123
AiD™ HBsAg ELISA	Diagnostic Kit for Hepatitis B Virus Surface Antigen (ELISA)	WB-1296 WB-12480	48319	EC Certificate IVDD 20 075 0120 EC Certificate IVDD 20 075 0121
AiD™ anti-HCV ELISA^{Plus}	Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	WC-31S96 WC-31S480	48365	EC Certificate IVDD 20 074 0116 EC Certificate IVDD 20 074 0117

which are LIST- A products (Classification rule according Annex II IVDD) 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 18113-1:2022, EN18113-2:2011, EN ISO 15223-1: 2016, EN 13612: 2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019, EN ISO 13485:2016, and CTS. The conformity assessment route with the requirements of the Directive 98/79/EC has been assessed following the procedure(s) outlined in the following annexes of the Directive 98/79/EC: **ANNEX IV**

The product is in compliance with common technical specifications as they are defined within COMMISSION DECISION (2009/886/EC) of 27 November 2009 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices.

The Design Examination and Full Quality Assurance System Certificates have been issued by:
bqs. s.r.o., Notified Body, NB number 2854,
Address: Študentská 1641/12, 91101 Trenčín, SLOVAKIA.

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe.
QARAD BV,
Address: Cipalstraat 3, 2440 Geel, Belgium

Digitally signed by Stoianova Elena
Date: 2025.09.12 22:08:35 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Ms. Zhao Lingzhi
(Vice General Manager and QA Director)
Beijing, 17 January, 2025

Revision History	Content	Date
v1	Establishment	6 April, 2022
v2	Product name revision of **AiD™ HIV 1+2 Ag/Ab ELISA^{Plus}**	24 June, 2024
v3	Updated regulation from EN ISO 18113-1:2011 to EN ISO 18113-1:2022	17 January, 2025