

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	Notified Body's Certificate no.
AiD™ HIV 1+2 Ab/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 EC Certificate IVDD 020 077 0113
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 0121 EC Certificate IVDD 20 075 0120
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 18113-1:2011, 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: Ciplastraat 3, 2440 Geel, Belgium



Ms. Zhao Lingzhi
(Vice General Manager and QA Director)
Beijing, 6 April, 2022

Revision History	Content	Date
v1	Establishment	6 April, 2022