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SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

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Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

EC Certificate IVDD 020 075 0120

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices
Annex IV excluding section 4 and section 6

Certificate holder: **Beijing Wantai Biological Pharmacy Enterprise Co., Ltd**

No.31 Kexueyuan Road, Changping District, Beijing 102206, China

Related audit report: AIVDD 2020NB074 I01

Other Facility(ies): -

The certificate was issued with respect to the following scope:

AiD™ HBsAg ELISA

This certificate is effective from 30 Mar 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 30 Mar 2022.

Certification has been authorized by

Digitally signed by Radovan Máčaj
Digitally signed by Varman Irina
Date: 2023.02.25 21:19:22 EET
Reason: MoldSign Signature
Location: Moldova

Radovan Macaj
Head of Notified body

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Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed examination of quality assurance system in accordance with Annex IV excluding section 4 and section 6 of the directive and found that the quality assurance system meets the requirements laid down by Annex IV. For the placing on the market of List A devices an EC design-examination certificate according to Annex IV section 4 is required. Please see also notes overleaf if any.

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Additional information on certification

Related to certificate number:

IVDD 020 075 0120

Description of product(s) within the certification scope:

AiD™ HBsAg ELISA is an enzyme-linked immunosorbent assay (ELISA) for qualitative detection of HBsAg in human serum or plasma. It is intended for screening of blood donors and for diagnosing of patients related to infection with hepatitis B virus.

Types/Categories/Models:	WB-1296 (96 wells), WB-12480 (480 wells)
Classification:	List A
Validity conditions:	-

This certificate is effective from 30 Mar 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 30 Mar 2022.

bqs.
Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed examination of quality assurance system in accordance with Annex IV excluding section 4 and section 6 of the directive and found that the quality assurance system meets the requirements laid down by Annex IV. For the placing on the market of List A devices an EC design-examination certificate according to Annex IV section 4 is required. Please see also notes overleaf if any.