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Notified body 2854 | SKTC-180

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

EC Certificate IVDD 020 075 0121

EC Design-Examination Certificate

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

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

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



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

Radovan Macaj
Head of Notified body

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 an examination of the design dossier in accordance with Annex IV section 4 of the directive and found that the design of the device conforms to the requirements laid down by Annex IV. For the placing on the market of List A devices an EC full quality assurance to Annex IV is required. Please see also notes overleaf if any.



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Additional information on certification

Related to certificate number:

IVDD 020 075 0121



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: -

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