EVPÚ®

**NOTIFIED BODY No. 1293**

# Verification of manufactured products

Directive 98/79/EC on In Vitro Diagnostic Medical Devices of the European Parliament and of the Council (IVDD), **Annex IV (6)** (*Module H*) transposed into "Slovak government decree No. 569/2001 Collection of Laws" as amended

## No. 41055V22/101/1/2012/CE

EVPÚ a.s., Notified Body No. 1293, has verified the manufactured products in accordance with IVDD Annex IV (6) and found that they conform to the requirements of IVDD.

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|---|---|
| **Manufacturer and Facility** | **Beijing Wantai Biological Pharmacy Enterprise Co.,Ltd., No.31 Kexueyuan Road, Changping District, Beijing, China, 102206** |
| **Device(s)** | **In-Vitro medical devices - ELISA kit** |
| **Type(s)** | **AiD™ HBsAg ELISA** |
| **Reference** | **WB-1296, WB-12480** |
| **Device(s)** | **in List A** |
| **Lot Number** | **B20210801** |
| **Relevant report(s)** | **40055/2012/C, 41055/2012/C, 40055/2012/D1, 40055/2012/C Rev.1, 40055/2012/C Rev.2, 4-1055V22/12/C** |
| **Expiration date** | **November 1st, 2022** |

EVPÚ, a.s. NOVÁ DUBNICA Notified Body No 1293

**Dušan Novotný**

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Date: 202
Reason: M
Location:

**Issued on** **September 10th, 2021** **Valid until** **November 1st, 2022**

**Manufacturer can affix the CE mark with number of Notified Body only in case devices are in comply with all relevant and effective Directives of European Parliament and of the Council.**

*The manufacturer must inform EVPÚ a.s. of any plan for substantial changes in the design of the device(s), in construction of the device(s) or in the quality system of production in order to examine whether this Certificate remains valid.*

*This Certificate is valid until the date specified. Any significant changes in the design of the device(s), in construction of the device(s), in the quality system or amendments to the Directive 98/79/EC may render this Certificate invalid at an earlier date.*

*The product liability rests with the manufacturer or his representative in accordance with the Directive 85/374/EEC.*