EVPÚ

NOTIFIED BODY No. 1293

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices of the European Parliament and of the Council (IVDD), **Annex IV (4)** (*Module H*) transposed into "Slovak government decree No. 569/2001 Collection of Laws" as amended

No. 41055/101/1/2012/CE Rev.3

EVPÚ a.s., Notified Body No. 1293, has performed examination of the design dossier relating to the device in accordance with IVDD Annex IV (4) and found that the design of the device conforms to the requirements of IVDD.

Manufacturer and Facility	**Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. No. 31 Kexueyuan Road, Changping District, Beijing 102206, China**
Device(s)	**In-vitro medical devices – ELISA kit**
Type(s)	**AiD™ HBsAg ELISA**
Reference code(s)	**WB-1296, WB-12480**
Device(s)	**in List A**
Relevant report(s)	**41055/2012/C, 40055/2012/D1, 40055/2012/C Rev. 1, 40055/2012/C Rev. 2**

Marek H u d á k

Issued on June 14th, 2017
Valid from June 27th, 2017

Valid until May 22nd, 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.

Digitally signed by Varman Irina
Date: 2019.03.27 09:50:15 EET
Reason: MoldSign Signature
Location: Moldova

History of certification:

No.	Certificate No.:	Description:	Date:
1.	40055/101/1/2012/CE	Original certificates issued	June 27th, 2012
2.	40055/101/1/2012/CE Rev.1	Addition of new relevant report	July 1st, 2015
3.	40055/101/1/2012/CE Rev.2	Change of the address form	November 2nd, 2016
4	40055/101/1/2012/CE Rev.3	Recertification	June 14th, 2017

EVPÚ

NOTIFIED BODY No. 1293

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices of the European Parliament and of the Council (IVDD), **Annex IV excluding (4, 6)** *(Module H)* transposed into "Slovak government decree No. 569/2001 Collection of Laws" as amended

No. 40055/101/1/2012/CE Rev.3

EVPÚ a.s., Notified Body No. 1293, has audited the quality system in accordance with IVDD Annex IV and found that quality system meets the requirements of IVDD Annex IV.

Manufacturer and Facility	**Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. No. 31 Kexueyuan Road, Changping District, Beijing 102206, China**
Device(s)	**In-vitro medical devices – ELISA Kit**
Type(s)	**AiD™ HBsAg ELISA**
Reference code(s)	**WB-1296, WB-12480**
Device(s)	**in List A**
Relevant report(s)	**40055/2012/C, 40055/2012/D1, 40055/2012/C Rev.1, 40055/20102/C Rev.2**
Audit report(s)	**M030/10-7**

Marek H u d á k

Issued on June 14th, 2017
Valid from June 27th, 2017
Valid until May 22nd, 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. For placing on the market of List A devices covered by this certificate an EC Design-Examination Certificate according to IVDD Annex IV (4) is required. Surveillance audits according to IVDD, Annex IV (5) will be held to verify the validity of this Certificate.

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.

History of certification:

No.	Certificate No.:	Description:	Date:
1.	41055/101/1/2012/CE	Original certificates issued	June 27th, 2012
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