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. 40003/101/1/2014/CE

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	**Fortress Diagnostics Ltd.** **Unit 2C Antrim Technology Park, Belfast Road, CO. Antrim, BT41 1QS, Northern Ireland, United Kingdom**
Device(s)	**In vitro diagnostic device for the determination of hepatitis B virus surface antigen ELISA kit**
Type(s)	**HBsAg (HS) ELISA**
Product code	**BXE0743A (1 x 96 Tests)** **BXE0743C (5 x 96 Tests)**
Device(s)	**in List A**
Relevant report(s)	**40003/2014/C**
Audit report(s)	**M004/2014**

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

Marek H u d á k

Issued on **April 7th, 2014** **Valid until** **June 26th, 2017**

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.