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. 41021/101/1/2014/CE

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	**Fortress Diagnostics Ltd.,** **Unit 2C, Antrim Technology Park, Belfast Road, Co. Antrim, BT41 1QS, Northern Ireland, United Kingdom**
Device(s)	**In Vitro Diagnostic Medical Device for determination of HIV 1+2 Antibody Elisa Kit (3rd generation)**
Type(s)	**anti-HIV 1+2 ELISA**
Catalogue No:	**BXE0793A (1x96 tests), BXE0793C (5x96 tests)**
Device(s)	**in List A**
Relevant report(s)	**40021/2014/C**

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

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Issued on **June 25th, 2014** **Valid until** **May 5th, 2019**

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.