NATIONAL CENTRE FOR PUBLIC HEALTH AND PHARMACEUTICALS
Directorate General for Health Licensing and Innovation Technology Medical
Technology Department

Register No: NNGYK/GYSZ/9516-2/2024
Registration No: HU/CA01/9516/2024 **Subject**: Certificate of registration **Administrator**: Sólyom Cintia/KD
Please refer to the number above in your reply!

International Supply Solutions Korlátolt Felelősségű Társaság
Sándor Pálos

Budapest
Váci út 76.1. ép. 4. 407
1133

Tax number: 32098802-2-41

OFFICIAL CERTIFICATE
CERTIFICATE OF REGISTRATION

Acting on behalf of the National Centre for Public Health and Pharmacy (hereinafter: NNGYK), pursuant to Section 16 (1g) of Decree 8/2003 (13.III.) of the Hungarian Federal Ministry of Health and Social Affairs (hereinafter: R.) on in vitro diagnostic medical devices (hereinafter: R.), which adopts Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices, **International Supply Solutions Korlátolt Felelősségű Társaság** (registered office: 1133 Budapest Váci út 76.1. ép. 4. 407, tax number: **32098802-2-41**, hereinafter referred to as "**the distributor**") to register the following in vitro diagnostic medical device(s)

i g a z o l o m:

Category of device(s) according to ISO 15225:2000: IVD devices.
Name of the device(s):

Serial number	Instrument name*	Catalogue/Reference/Item number (identifier)*	Risk class*	Name of manufacturer*	EC/REP name
1.	RealBest-Genetics Hemostasis PAI-1/ITGB3	D-3833	General IVD	JSC Vector-Best	Bioron GmbH

Serial number	Instrument name*	Catalogue/Reference/Item number (identifier)*	Risk class*	Name of manufacturer*	EC/REP name
2.	RealBest-Genetics HLA-B*27	D-3836	General IVD	JSC Vector-Best	Bioron GmbH
3.	RealBest DNA Staphylococcus aureus/mecA/lukS-PV	D-5603	General IVD	JSC Vector-Best	Bioron GmbH

An official certificate attesting to the data entered in the register is valid until revoked, provided that the data it contains remain unchanged.

The registration was based on the manufacturer's declaration that the device(s) is/are an in vitro diagnostic medical device(s) covered by the R. and already registered/certified in a Member State of the European Union.

Based on the above statements, the NNGYK has granted the request for registration, while stressing that it does not examine each and every notification, and therefore registration does not and cannot imply approval of the contents of the notification. The present certificate is therefore neither an approval nor a consent.

The Client has paid the administrative service fee of HUF 66 000 pursuant to **Annex 1, point II.12 of NM Decree 50/1996 (XII. 27.)** on the fees payable for certain state administrative procedures and services of an administrative nature in the welfare sector.

The possibility of appeal is excluded by **Section 116 (4) (d)** of **Act CL** of **2016** on the General Administrative Procedure (hereinafter: the "**General Administrative Procedure Act"**), while the possibility of initiating an administrative lawsuit is provided for by **Section 114 (1)** of the **General Administrative Procedure Act.** Subject to the provisions of Articles 94-95 of the **Ákr,** I have taken the decision contained in the present certificate of authority within the scope of the powers granted by Article 16 (1g) of the R., acting on the basis of the designation provided for in **Article 8 (13) of Government Decree No. 333/2023 (20.VII.) of 20 July** on the National Centre for Public Health and Pharmacy.

Budapest, according to electronic time stamp

Dr Müller Cecília
for and on behalf of the
National Medical Officer

Dr. Enikő Szabó
Deputy National Medical Officer

Receive it electronically:

1. **International Supply Solutions Korlátolt Felelősségű Társaság** (registered office: 1133 Budapest Váci út 76.1. building 4. 407. tax number: **32098802-2-41)**
2. **Archives**

Aláíró: Dr. Szabó Enikő
(2024.03.20.)