

EC CERTIFICATE

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV excluding (4, 6)

No. 7-037-400-2107

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.
certifies that the manufacturer:

**Institute of Isotopes Co. Ltd.
Konkoly-Thege Miklós út 29-33.
1121 Budapest
Hungary**

for the products / product categories:

Immunoassay kits for determination of tumor markers

Test kits for Down's Syndrome (Trisomy 21) risk assessment

applies a quality system which meets the requirements of Directive 98/79/EC on in vitro diagnostic medical devices, Annex IV.

Registry number of the related audit report: **NE/1104/2021**

This certificate is valid until **2025-05-26** supposed that the results of the regular yearly surveillance audits are satisfactory.

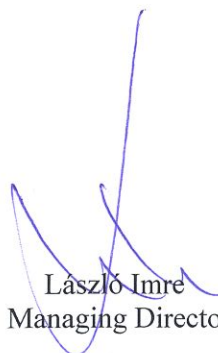
Issued by NEOEMKI LLC. as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 2

First issued: 2021-07-13

Budapest, 2022-05-03


László Imre
Managing Director



EMKI 2822

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu



ATTACHMENT TO EC CERTIFICATE

Page 1 of 1

Additional information for Certificate No. 7-037-400-2107

The certificate is valid for the following products:

Immunoradiometric (IRMA) kits for the determination of human prostate specific antigen (PSA)

Types	Code
hPSA [I-125] IRMA KIT	RK-10CT
free PSA [I-125] IRMA KIT	RK-85CT

Test kits for Down's Syndrome (Trisomy 21) risk assessment

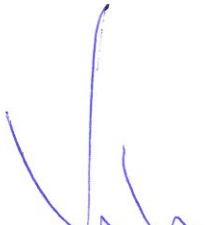
Components	Code
PAPP-A [I-125] IRMA KIT	RK-4CT
AFP [I-125] IRMA KIT	RK-800CT
FREE β -hCG [I-125] IRMA KIT	RK-820CT

The detailed description of the products is kept by NEOEMKI LLC. under No. NE/1104/2021.

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