

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.

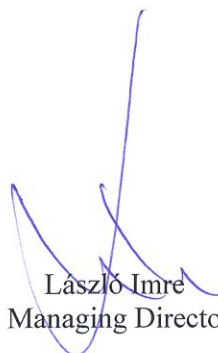
Issued by NEOEMKI LLC. as a Notified Body with identification number **1011**.

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

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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)

<i>Types</i>	<i>Code</i>
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

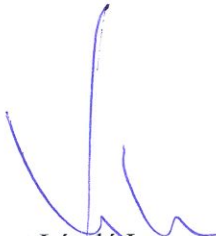
<i>Components</i>	<i>Code</i>
PAPP-A [I-125] IRMA KIT	RK-4CT
AFP [I-125] IRMA KIT	RK-800CT
FREE β -hCG [I-125] IRMA KIT	RK-820CT

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

Issue: 2

Date: 2022-05-03

First issued: 2021-07-13


László Imre
Managing Director



EMKI

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
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www.emki.hu



Mihály Lakatos
Managing Director

Budapest, 17th February 2023
Reference: NE/1104-44/2023

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

CONFIRMATION LETTER

NEOEMKI LLC. hereby confirms that Institute of Isotopes Co. Ltd. (address: Konkoly-Thege Miklós út 29-33, 1121 Budapest, Hungary; company registration number: 01-09-261264) submitted a change notification for approval.

Affected certificate: 7-037-400-2107

Change request ID: NE/1104-39/2023

Date of notification of change request: 6th of February 2023

The change affected: the range of the certified products (limitation)

Brief description of the change: components of the Test kits for Down's Syndrome (Trisomy 21) risk assessment are excluded from the scope of the certification

<i>Name of the kit</i>	<i>Code of the kit</i>
PAPP-A [1-125] IRMA	RK-4CT
FREE 3-hCG [1-125] IRMA	RK-82OCT
AFP [1-125] IRMA	RK-800CT

Schedule of introduction of the change:

Kit:	LOT	Start of production:	Getting into stock:	Expiry date:
RK-4CT	230399	06.03.2023	16.03.2023	14.05.2023
RK-800CT	230231	06.03.2023	16.03.2023	14.05.2023
RK-82OCT	230255	06.03.2023	16.03.2023	14.05.2023

Assessment of the significance of the change

Based on the data indicated in the submitted change notification, NEOEMKI LLC, the issuer of the certificate affected by the change, hereby confirm that **the change is qualified non-significant** in accordance with Article 110 (3) of Regulation (EU) 2017/746 or MDCG 2022-6 guideline.

Following the introduction of the change, the above mentioned certificate may remain valid, among the products previously covered by the certificate, the Immunoradiometric (IRMA) kits, namely hPSA [I-125] IRMA KIT – RK-10CT and free PSA [I-125] IRMA KIT – RK-85CT, not affected by the change may be lawfully placed on the market and put into service until conditions laid down in Article 110 (3) of Regulation (EU) 2017/746 are met.

The PAPP-A [I-125] IRMA KIT – RK-4CT and the FREE β -hCG [I-125] IRMA KIT – RK-820CT and the AFP [I-125] IRMA KIT – RK-800CT may no longer form a set of test kits for Down's Syndrome (Trisomy 21) risk assessment or be considered part of such a set.

The effects of the change regarding the certified products and/or QMS, and the existence of all the conditions necessary to maintain the certificate shall be verified by the certification body as part of its surveillance activity.

This confirmation letter corrects information on the affected certificate but does not represent the issuance of a "supplemented certificate" as this is prohibited under Article 110 (3) of Regulation (EU) 2017/746.

This confirmation letter is by no mean considered as a new, modified, amended, extended or supplemented certificate, as issuing of new certificates, including modified, amended or supplemented certificates is prohibited under Article 110 (3) of Regulation (EU) 2017/746.

This conformation letter has been issued upon request of the manufacturer and valid together with the corresponding certificate only.



Imre László
Managing Director

