

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 **2024-05-26** 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.

Budapest, 2021-07-13


László Imre
Managing Director



EMKI 2770

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.

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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)

Types:

total PSA kit: RK-10CT

free PSA kit: RK-85CT

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

Components:

PAPP-A IRMA kit: RK-4CT

AFP IRMA kit: RK-800CT

free betahCG IRMA kit: RK-820CT

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

Issue: 1

Date: 2021-07-13

First issued: 2021-07-13


László Imre
Managing Director



EMKI