

# EC CERTIFICATE

## Full Quality Assurance System

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

No. 7-026-400-1607

National Institute of Pharmacy and Nutrition  
Directorate of Device Testing and Clinical Engineering (EMKI)

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: **53-109-2007**

This certificate is valid until **2021-07-12** supposed that the results of the regular yearly surveillance audits are satisfactory.

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

This certificate is valid only with the attachment.

Budapest, 2016-07-13

  
Deputy General Director

  
  
Head of EMKI



EMKI 1507

The authenticity and validity of the certificate are verifiable at EMKI.

## ATTACHMENT TO EC CERTIFICATE

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### Additional information for Certificate No. 7-026-400-1607

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:

Unconjugated Estriol RIA kit: RK-3CT

PAPP-A IRMA kit: RK-4CT

hCG RIA kit: RK-770CT

AFP IRMA kit: RK-800CT


free beta hCG IRMA kit: RK-820CT


The detailed description of the products is kept by EMKI under No. 53-109-2007.


Issue: 1

Date: 2016-07-13

First issued: 2016-07-13

  
Deputy General Director

  
Head of EMKI

  
EMKI