



# CERTIFICATE

*This certifies that the Quality management system for medical devices of company*

**Institute of Isotopes Co., Ltd.**

Konkoly-Thege Miklós út 29-33., H-1121 Budapest, Hungary



*has been assessed by 3EC International and found to be in conformance with the following standard:*

**EN ISO 13485:2016**

*for the following scope:*

**DEVELOPMENT, MANUFACTURING AND DISTRIBUTION OF RADIOACTIVE IMMUNOASSAY KITS**

Certificate No.: M-0616/26

Date of issuance: May 15th, 2026

Original date of approval: December 9th, 2009

Date of Recertification audit: May 4th - 6th, 2026

This certificate is valid from **June 6th, 2026** to **June 5th, 2029** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a. s., Hraničná 18, 821 05 Bratislava, Slovak Republic



Dr. Katarína Tomin Srdošová  
Head of Certification Body 3EC International a. s.

Certification body 3EC International a. s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices covered by EA MLA and IAF MLA.