

QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-455-135-1706

The **Directorate of Device Testing and Clinical Engineering (EMKI)**
as a Certification Body with ID No. NAH-4-0096/2016
accredited by the National Accreditation Authority for management system certification
certifies that the quality management system applied by

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

meets the requirements of standard

EN ISO 13485:2016

in the field:

**Development, manufacturing and distribution
of radioactive immunoassay kits**

Registry number of the related audit report: **43-038-2009**

This certificate is valid until **2020-06-05** supposed that the results of the regular yearly surveillance audits are satisfactory.

The Company has been certified by EMKI since 2009-12-09.

Issue: 2

First issued: 2017-06-06

Budapest, 2018-12-18



Head of EMKI



EMKI 2145

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

Eszközminősítő és Kórháztechnikai Igazgatóság
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EMKI