

QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-552-135-2107

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.

as a Certification Body with ID No. NAH-4-0009/2021/K
accredited by the National Accreditation Authority for management system certification

certifies that the quality management system applied by

REAGENS Kft.
1155 Budapest, Wysocki u. 1.
Hungary

meets the requirements of standard

EN ISO 13485:2016

in the field:

**Manufacture and distribution
of reagents for haematology, of auxiliary materials for serology, of red blood
cell tests for reverse typing, antibody screening and identification, and of
control materials for blood typing serology;
Distribution of reagents for blood typing serology and
other diagnostic reagents**

Registry number of the related audit report: NE/1014/2021

This certificate is valid until **2024-07-04** supposed that the results of the regular yearly
surveillance audits are satisfactory.

The Company has been certified since 2006-07-04.

Budapest, 2021-07-05


László Imre
Managing Director



EMKI 2768

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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