QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-602-135-2407

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/1014/2024

This certificate is valid until 2027-07-04 supposed that the results of the regular yearly surveillance audits are satisfactory.

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

Budapest, 2024-07-04

László Imre Managing Director





EMKI 2918

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.