

QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-487-135-1807

The **Directorate of Device Testing and Clinical Engineering (EMKI)**
as a Certification Body for quality 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: **43-016-2007**

This certificate is valid until **2021-07-04** supposed that the results of the regular yearly surveillance audits are satisfactory.

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

Budapest, 2018-07-05



Head of EMKI



EMKI 2039

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

Eszközminősítő és Kórháztechnikai Igazgatóság
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EMKI