

EC CERTIFICATE

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV excluding (4, 6)

No. 7-021-400-1507

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.
certifies that the manufacturer:

REAGENS Kft.
Wysocki u. 1.
1155 Budapest
Hungary

for the products / product category/ies:

Screening and panel cells for screening and identification of irregular anti-erythrocytic antibodies

ABO grouping cell kits

Control material for blood typing serology

applies a quality system which meets the requirements of Directive 98/79/EC on in vitro diagnostic medical devices, Annex IV.

Registry number of the related audit report: **NE/1014/2020**

This certificate is valid together with EC Design-Examination Certificates according to Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV (4) No. **7-022-404-1507** and **7-023-404-1507**.

This certificate is valid until **2021-01-14**.


Issued by NEOEMKI LLC. as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 2

First issued by the National Institute of Pharmacy and Nutrition Directorate of Device Testing and Clinical Engineering (EMKI) on 2015-07-15.

Budapest, 2020-07-01


László Imre
Managing Director



EMKI 2391

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

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
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EMKI

ATTACHMENT TO EC CERTIFICATE

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Additional information for Certificate No. 7-021-400-1507

The certificate is valid for the following products:

Product	Types and variants	Remarks
Screening cells for antibody screening	ReaCell I, II, III	
	ReaCell IP, IIP, IIIP	papainized
Panel cells for antibody identification	ReaCell Panel	
	ReaCell Panel P	papainized
ABO grouping cell kits	ReaCell AB0	List A
Control material for blood typing serology	Rea IQC Total Blood Kit	List A

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László Imre
Managing Director



EMKI