

EC DESIGN-EXAMINATION CERTIFICATE
Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV (4)

No. 7-023-404-1507

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.
certifies that the following manufacturer's

REAGENS Kft.
Wysocki u. 1.
1155 Budapest
Hungary

product's **Control material for blood typing serology**

following model's

Rea IQC Total Blood Kit

design dossier conforms to the requirements of Directive 98/79/EC on in vitro diagnostic
medical devices.

Registry number of the report on the examination of the design dossier: **NE/1014/2020**

This certificate is valid only together with EC Certificate according to Directive 98/79/EC on In
Vitro Diagnostic Medical Devices, Annex IV excluding (4,6) No. 7-021-400-1507.

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: 5

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 2395

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.

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu

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Additional information for Certificate No. 7-023-404-1507

The certificate is valid for the following variants:

<i>REF</i>	<i>Product name</i>	<i>Kit / components</i>	<i>Concentration</i>
44100	Rea IQC Total Blood Kit	4 × 6 ml	25-30%
44101	Rea IQC 1	6 ml	
44102	Rea IQC 2	6 ml	
44103	Rea IQC 3	6 ml	
44104	Rea IQC 4	6 ml	
44110	Rea IQC Total Blood Kit	4 x 4 ml	25-30%
44111	Rea IQC 1	4 ml	
44112	Rea IQC 2	4 ml	
44113	Rea IQC 3	4 ml	
44114	Rea IQC 4	4 ml	
44120	Rea IQC Total Blood Kit	2 x 4 ml	25-30%
44113	Rea IQC 3	4 ml	
44114	Rea IQC 4	4 ml	

Issue: 5

Date: 2020-07-01

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<i>REF</i>	<i>Product name</i>	<i>Kit / components</i>	<i>Concentration</i>
44130	Rea IQC Total Blood Kit	4 × 6 ml	15%
44131	Rea IQC 1	6 ml	
44132	Rea IQC 2	6 ml	
44133	Rea IQC 3	6 ml	
44134	Rea IQC 4	6 ml	
44140	Rea IQC Total Blood Kit	4 x 4 ml	15%
44141	Rea IQC 1	4 ml	
44142	Rea IQC 2	4 ml	
44143	Rea IQC 3	4 ml	
44144	Rea IQC 4	4 ml	

The product list is kept by EMKI under No. 53-445-2011.

Issue: 5

Date: 2020-07-01

First issued: 2015-07-15


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