

EC DESIGN-EXAMINATION CERTIFICATE

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

No. 7-023-404-1507

National Institute of Pharmacy and Nutrition
Directorate of Device Testing and Clinical Engineering (EMKI)

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: **53-445-2011**

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: **2020-07-14**

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

This certificate is valid only with the attachment.

Issue: 2

First issued: 2015-07-15

Budapest, 2016-08-03



Deputy General Director




Head of EMKI



EMKI 1515

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

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet
National Institute of Pharmacy and Nutrition
Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

H-1051 Budapest, Zrínyi u. 3. Fax: +36 1 886 94 60, Telefon: +36 1 225 27 39
H-1097 Budapest, Albert Flórián út 3/A, E-mail: cert@emki.hu, Web: www.emki.hu



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ATTACHMENT TO EC DESIGN-EXAMINATION CERTIFICATE

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

The certificate is valid for the following variants:

REF	Product name	Kit / components	Concentration
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	

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


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