EC CERTIFICATE

Digitally signed by Luncaşu Svetlana
Date: 2019.03.20 10:42:04 EET
Reason: MoldSign Signature
Location: Moldova

Rapid Labs Limited

Unit 2 & 2a Hall Farm Business Centre
Church Road, Little Bentley, Colchester, CO7 8SD

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:
The manufacture of in vitro diagnostic reagents for identification of blood groups

Device Classification:
Annex II, List A and B

Device Descriptions:
Please refer to Attachment 1

Model:
Please refer to Attachment 1

File Number	A28443	Cycle Start Date	23 May 2017
Certificate No.	810.170523	Effective Date	23 May 2017
		Expiry Date	22 May 2022

Authorised by

C.H. Tonkin
Certification Manager
For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per Project No. 4787988312, following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with (1) attachments listing model numbers and (0) addendums listing additional locations covered by this certificate.

Notified Body

0843

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

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Attachment <1 of 1>

The products detailed below are covered under the scope of this certificate

Device Description	Model	Classification
Anti-A Monoclonal	BC-A10/BC-A10X10	Annex II List A
Anti-B Monoclonal	BC-B10/BC-B10X10	Annex II List A
Anti-A,B Monoclonal	BC-AB10/BC-AB10X10	Annex II List A
Anti-D Monoclonal	BC-D10/BC-D10X10	Annex II List A
Anti A, B, AB, D	BC-ABOD10	Annex II List A
Anti A, B, D	BC-ABD10	Annex II List A
Anti-Human Globulin Polyspecific	BC-AHG10/BC-AHG10X10	Annex II List B

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