EC CERTIFICATE

Rapid Labs Limited

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

EC Design - Examination Certificate

Annex IV, section 4 of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Device Description:
In vitro diagnostic reagents for identification of blood groups

Device Classifications:
Annex II List A

Model Type:
Please refer to Attachment: 1

We hereby declare that a design examination has been carried out on the device(s) listed, following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV section 4 of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the design of the device(s) listed conforms with the relevant provisions of Annex IV section 4 of the aforementioned directive as transposed into national legislation. This certificate is issued with 1 attachment listing product references.

Digitally signed by Munteanu Iuliana
Date: 2019.09.06 13:53:34 EEST
Reason: MoldSign Signature
Location: Moldova

File Number	A28443	Cycle Start Date	May 24, 2018
Certificate Number	811.180524	Effective Date	May 24, 2018
Initial Issue Date	November 15, 2016	Expiry Date	May 23, 2023

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

Check Certificate Status: here

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:

Model/Type	Classification	G/UMDN Code
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 (IgG & IgM), BC-D10/BC-D10X10	Annex II List A	-
Anti A, B, AB, D (lgG & lgM) kit, BC-ABOD10	Annex II List A	-
Anti A, B, D (lgG & lgM) kit, BC-ABD10	Annex II List A	-

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