



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.

| | | | |
|--------------------|-------------------|------------------|--------------|
| 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



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Status: [here](#)

Notified Body
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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 (IgG & IgM) kit, BC-ABOD10 | Annex II List A | - |
| Anti A, B, D (IgG & IgM) kit, BC-ABD10 | Annex II List A | - |

| | | | |
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