



EC CERTIFICATE

Lab21 Healthcare Ltd,

Unit 29 Dreadnought Trading Estate, Bridport, Dorset, DT6 5BU United Kingdom

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, section 3 of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:

In vitro diagnostic reagents for blood grouping

Device Classification:

Annex II, list A and B

Device Descriptions⁹

Blood grouping reagents

Model:

See attachment

| | | | |
|-----------------|------------|------------------|-----------------|
| File Number | A28334 | Cycle Start Date | 15 January 2016 |
| Certificate No. | 777.160404 | Effective Date | 04 April 2016 |
| | | Expiry Date | 14 January 2019 |

Authorised by

Brian Rodgers
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 report SR3130830.863936, 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 attachment listing model numbers and.

Notified Body

0843

IVDD A4 S3 FQ OBL 00-NB-F0051 Issue: 4.0

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 (2 brands) | | Classification |
|----------------------------------|------------------|--------|------------------|
| | Plasmatec | Biotec | |
| Anti-A | ABO/010 | 1/008 | Annex II, list A |
| Anti-B | ABO/020 | 1/018 | Annex II, list A |
| Anti-A, B | ABO/030 | 1/028 | Annex II, list A |
| Anti-Rh D IgM Monoclonal | RH/010 | 1/039 | Annex II, list A |
| Anti-Rh D (IgG + IgM) Monoclonal | RH/020 | 1/038 | Annex II, list A |
| Anti Human Globulin | AHG/010 | 1/312 | Annex II, list B |

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