EC Declaration of Conformity

DESCRIPTON AND PRODUCT CODE

Product Description	Product Code
ASO Latex Test Kit	ASO/010 & ASO/012
Brucella Antigen/Antibody Assays	FA/018 & FA/020
CRP Latex Test Kit	CRP/010 & CRP/012
HCG Latex Test Kit	DPT/010 & DPT/012
IM Latex Test Kit	IM/010 & IM/012
Proteus Antigen/Antibody Assays	FA/022, FA/024 and FA/026
RA Latex Test Kit	RA/010 & RA/012
Rotavirus Test Latex Kits	ROV/010 & ROV/012
RPR Antigen Test Kit	RPR/010 & RPR/012
Salmonella Antigen/Antibody Assays	FA/002-FA/016, FA/040 & FA/042 Control Reagents FA/030 & FA/032
SLE Latex Test Kit	SLE/010 & SLE/012
Staphylococcus Latex Test Kit	STA/010 & STA/012
Streptococcus Grouping Latex Reagents	STE/010
TPHA test Kit	TPHA/010, TPHA/020 & TPHA/100
VDRL Carbon Antigen Test Kit	CA/010, CA/012, CA/014 & CA/015

Lab21 Healthcare Ltd declares that the products listed above are in conformity with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also UK Statutory Instrument 2002 No 618: The Medical Devices Regulations 2002) and conforms to standards ISO 9001:2008 and ISO 1485:2012.

This declaration of conformity is issued under the sole responsibility of Lab21 Healthcare Ltd and is valid from 26 Feb 2016.

Signed .....
Chief Executive Officer

Date.....10th March 2016.....

Lab21 Healthcare Limited, Unit 29 Dreadnought Trading Estate Bridport, Dorset DT6 5BU, UK.

EC Declaration of Conformity

PRODUCT CODE (S): **AHG/010**

DESCRIPTION: **Anti – Human Globulin**

Lab21 Healthcare Ltd declares that the AHG/010 in vitro diagnostic reagent has been classified as List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC) and the Commission Decision on Common Technical Specifications 2009/108/EC.

and is in conformity with the national standards transposing harmonised standards:

- ❑ BS EN 980:2008
- ❑ BS EN ISO 13485:2012
- ❑ BS EN 13612:2002
- ❑ BS EN 13640:2002
- ❑ BS EN 13641:2002
- ❑ BS EN ISO 14971:2012
- ❑ BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex IV of Directive 98/79/EC and was carried out by UL International (UK) Ltd, Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey GU3 1LR, United Kingdom, Notified Body Number 0843.

The certificates issued by UL-UK Ltd to show compliance number 777.160115.

This declaration of conformity is issued under the sole responsibility of Lab21 Healthcare Ltd and is valid from 26 Feb 2016

Signed .....
Chief Executive Officer

Date..... 10th March 2016

Lab21 Healthcare Limited, Unit 29 Dreadnought Trading Estate Bridport, Dorset DT6 5BU, UK

EC Declaration of Conformity

PRODUCT CODE (S):	**ABO/010** **ABO/020** **ABO/030** **RH/010** **RH/020**
DESCRIPTION:	**Anti A monoclonal** **Anti B monoclonal** **Anti AB monoclonal** **Anti D IgM Monoclonal** **Anti D (IgG/IgM) Monoclonal**

Lab21 Healthcare Ltd declares the above in vitro diagnostic products has been classified as List A (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC) and the Commission Decision on Common Technical Specifications 2009/108/EC.

and is in conformity with the national standards transposing harmonised standards:

- ☐ BS EN 15223-1:2012
- ☐ BS EN ISO 13485:2012
- ☐ BS EN 13612:2002
- ☐ BS EN 23640:2015
- ☐ BS EN 13641:2002
- ☐ BS EN ISO 14971:2012
- ☐ BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex IV of Directive 98/79/EC and was carried out by UL International (UK) Ltd, Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey GU3 1LR, United Kingdom, Notified Body Number 0843.

The certificates issued by UL-UK Ltd to show compliance number 777.160115.

This declaration of conformity is issued under the sole responsibility of Lab21 Healthcare Ltd and is valid from 24 Feb 2016.

pp Signed ..... [Dr. ARI RAJU]
Chief Executive Officer QA/RA Manager

Date..... 24 Feb 2016.....

Lab21 Healthcare Limited, Unit 29 Dreadnought Trading Estate Bridport, Dorset DT6 5BU, UK.