

EU DECLARATION OF CONFORMITY

MANUFACTURER

Name	Lab 21 Healthcare Ltd
Address	UNIT 29, DREADNOUGHT TRADING ESTATE, BRIDPORT DORSET DT6 5BU
Country	UNITED KINGDOM

MEANS OF CONFORMITY FOR THE FOLLOWING PRODUCTS-

Lab 21 Healthcare Ltd declares that the products listed below 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 ISO13485:2012.

For Blood grouping antisera the conformity assessment procedure (route to compliance) to be followed is Annex II List A of the IVD Directive 98/79/EC

PRODUCT IDENTIFICATION

Product name	Anti Human Globulin
Brand	Plasmatec
Cat. Number	AHG/010 & versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	13 03 04 04 00

Product name	Anti A Monoclonal Sera
Brand	Plasmatec
Cat. Number	ABO/010 & versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	13 03 01 02 00

Product name	Anti A,B Monoclonal Sera
Brand	Plasmatec
Cat. Number	ABO/030 & versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	13 03 01 02 00

Product name	Anti B Monoclonal
Brand	Plasmatec
Cat. Number	ABO/020
Batch/Serial Nr (if applicable)	N/A
Product Classification	13 03 01 02 00

Product name	Anti D IgM Monoclonal
Brand	Plasmatec
Cat. Number	RH/010
Batch/Serial Nr (if applicable)	N/A
Product Classification	13 03 02 01 00

Product name	Anti D IgM/IgG BLEND
Brand	Plasmatec
Cat. Number	RH/020
Batch/Serial Nr (if applicable)	N/A
Product Classification	13 03 02 01 00

Product name	Bovine Albumin
Brand	Plasmatec
Cat. Number	BA/010 Bovine Albumin 30%,
	BA/020 Bovine Albumin 22%
Product Classification	13 03 04 06 00

MEANS OF CONFORMITY FOR THE FOLLOWING PRODUCTS-

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PRODUCT IDENTIFICATION

Product name	ASO Latex Test Kit
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	ASO/010, ASO/012 & Versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	12 11 01 05 00

Product name	Brucella Antigen/Antibody assays
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	FA/018 & FA/020 and versions thereof Control reagents FA/030B, FA/030 and FA/032
Batch/Serial Nr (if applicable)	N/A
Product Classification	15 01 90 01 00

Product name	CRP Latex Test Kit
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	CRP/010, CRP/012 & versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	12 11 01 09 00

Product name	E Coli 0157 Latex Test Kit
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	ECO/010, ECO/012 & versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	15 01 90 70 00

Product name	HCG Latex Test Kit
Brand	Plasmatec, Antec, Alpha Shield, Concept 200 & others as applicable
Cat. Number	DPT/010, DPT/012 & versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	12 05 02 05 00

Product name	IM Latex Test Kit
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	IM/010, IM/012 and versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	15 70 90 03 00

Product name	Proteus Antigen/Antibody assays
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	FA/022, FA/024 & FA/026 and versions thereof Control reagents FA/030P, FA/030 and FA/032
Batch/Serial Nr (if applicable)	N/A
Product Classification	15 01 90 12 00

Product name	RA Latex Test Kit
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	RA/010, RA/012 and versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	12 11 01 10 00

Product name	Rotavirus Test Latex Kits
Brand	Plasmatec, Antec, Alpha Shield and others as applicable
Cat. Number	ROV/010, ROV/012 & versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	15 04 80 06 00

Product name	RPR Antigen test kit
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	RPR/010, RPR/012 & versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	15 01 03 03 00

Product name	Salmonella Antigen/Antibody assays
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	FA/002 – FA/016, FA/040 & FA/042 and versions thereof Control reagents FA/030 and FA/032
Batch/Serial Nr (if applicable)	N/A
Product Classification	15 01 10 03 00

Product name	SLE Latex Test Kit
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	LE/010, LE/012 and versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	12 10 01 16 00

Product name	Staphylococcus Latex Test Kit
Brand	Plasmatec, Antec & Alpha Shield & others as applicable.
Cat. Number	STA/010, STA/012, STA/020 & Versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	14 02 03 03 00

Product name	Streptococcus Grouping Latex Reagents
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	STE/010 and all versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	14 02 03 02 00

Product name	TPHA test Kit
Brand	Plasmatec, Antec, Alpha Shield & others as applicable
Cat. Number	TPHA/010, TPHA/020, TPHA/100 and versions thereof
Batch/Serial Nr (if applicable)	N/A
Product Classification	15 01 03 03 00

Product name	Uripath Urinalysis Strips up to 11 parameters
Brand	Plasmatec (Uripath)
Cat. Number	various
Batch/Serial Nr (if applicable)	N/A
Product Classification	11 70 02 02 00

Product name	Uripath Urinalysis Strips up to 11 parameters and automated analyzer
Brand	Plasmatec (Uripath)
Cat. Number	URI – 10 + Leuko and versions from 1 to 11 parameters
Batch/Serial Nr (if applicable)	N/A
Product Classification	11 70 02 02 00

Product name	Uripath CR 100 plus automated Urine analyzer
Brand	Plasmatec (Uripath)
Catalogue Number	
Batch/Serial Nr (if applicable)	N/A
Product Classification	21 01 10 01 00

Product name	VDRL Carbon Antigen test kit
Brand	Plasmatec, Antec, Alpha Shield and others as applicable
Cat. Number	CA/010, CA/012 & CA/014 and versions
Batch/Serial Nr (if applicable)	N/A
Product Classification	15 01 03 03 00

SIGNATURE

Place and date	Lab 21 Healthcare Ltd, Bridport 02/12/2014
Signature	P.J. Winton
Name	P.J. Winton BSc Hons
Title	Production Director – Emerging Markets