



DECLARATION OF CONFORMITY

Product Identification	
IFA Range of Products	Product Code
Crypto CEL 50T kit, Crypto CEL Reagent – Standard Crypto CEL Reagent – FAST Crypto Positive Control Slide	KR1 RR1 RR1F CR
Giardia CEL 50T kit, Giardia CEL Reagent – Standard Giardia CEL Reagent Concentrate (10x) Giardia Positive Control Slide	KG1 RG1 RG1CN G
Crypto/Giardia (C/G) CEL 50T kit, C/G CEL Reagent – Standard C/G CEL Reagent FAST C/G Positive Control Slide	KR2 RR2 RR2F CG
Pneumo CEL 50T kit Pneumo CEL Indirect 50T kit Toxo CEL 50T kit	KP1 KP2 KT1
C/G Mounting Fluid	RMG

Product Identification	
ELISA Range of Products	Product Code
Malaria Ag CELISA – Standard Malaria Ag CELISA – Bulk kit Quantimal™ Ultra-sensitive Pf-HRP2 CELISA -Standard Quantimal™ Ultra-sensitive Pf-HRP2 CELISA – Bulk	KM2 KM2BP KM8 KM8-BP
Quantimal pLDH Malaria CELISA – Standard Quantimal pLDH Malaria CELISA – Bulk	KM7 KM7BP
Pan Malaria Antibody CELISA kit T.cruzi IgG CELISA Toxocara IgG CELISA Entamoeba Path CELISA Giardia CELISA Bm14 Filariasis Antibody CELISA Tropbio Filariasis Antigen ELISA	KMC3 KT4 KT3 KE1 KG2 KF3 KF1, KF2
Other Products	
Tropbio Filter Paper Blood Collection Discs DOAC-Stop	FP HX9904

MANUFACTURER		
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CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Standards Applied
Self-certification	Annex III EU 98/79/EC Council Directive on In Vitro Diagnostic Medical Devices	ISO 13485:2016

CELLABS declares the above mentioned products meet the provision of the Council Directive 98/79 EC for *in vitro* diagnostic medical devices.

Company Representative: Diane Dogcio Hall
Title: Quality Assurance & Regulatory Affairs Manager

Signature: 
Date: 10 February 2018

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