

EC – Declaration of Conformity

We, LDBIO Diagnostics, 19A rue Louis Loucheur, 69009 Lyon, France, hereby confirm that we have installed a quality management system according to the harmonised standards ISO 9001:2008 and NF EN ISO 13485:2012. Our quality management system has been certified for compliance with said standards by the LNE/GEMED (Certification no. 9742 rev. 5, valid until 20 July 2018).

Compliance with additional requirements of Annex IV (Directive 98/79 EC) for products classified as either Annex II list B has been certified by the notified bodies LNE/GMED 0459 (Certification 9760 rev. 4, valid until 20 July 2018).

We further confirm that the IVD products listed in Attachment 1 are designed, manufactured and controlled by us in accordance with the European Directive 98/79 EC and that they meet the essential requirements according to Annex I of said Directive. Applicable conformity assessment procedures according to Annex III or Annex IV.3, whatever applicable, of said directive have been completed for these products.

With the **CE** mark on the listed products, we declare that the products are in conformity with the applicable Directive 98/79/EC and harmonised standards.

Lyon, le 24/01/2018
LDBIO DIAGNOSTICS
Denis Limonne
Managing Director

Attachment 1: Products List

Product name	Product reference	Classe (Directive 98/79 CE)
TOXOPLASMA WB IgG-IgM	TOP-WB12GM, TOP-WB24GM, TOP-WB96GM	Test listed in Annex II, List B
TOXOCARA WB IgG	TXA-WB12G, TXA-WB24G, TXA-WB96G	
LEISHMANIA WB IgG	LES-WB12G, LES-WB24G, LES-WB96G	
ECHINOCOCCUS WB IgG	ECH-WB12G, ECH-WB24G, ECH-WB96G	
CYSTICERCOSIS WB IgG	CYS-WB12G, CYS-WB24G, CYS-WB96G	
SCHISTO II WB IgG	SCH II-WB12G, SCH II-WB24G, SCH II WB96G	
TRICHINELLA ES WB IgG	TRI ES-WB12G, TRI ES-WB24G, TRI ES-WB 96G	
FASCIOLA ES WB IgG	FAS ES-WB12G, FAS ES-WB24G, FAS ES-WB96G	
LDBIO TOXO II IgG	TOXO II 12G, TOXO II 24G, TOXO II WB96G	Test listed in Annex II, List B
ASPERGILLUS WB IgG	ASP-WB12G, ASP-WB24G, ASP- WB96G	
CHAGAS WB IgG	CHA-WB12G, CHA-WB24G, CHA- WB96G	
SCHISTOSOMA ICT IgG-IgM	BILZ Ab ICT20	
TOXOPLASMA ICT IgG-IgM	TOXO Ab ICT20	Test listed in Annexe II, Liste B