

## EC - Declaration of Conformity

We, LDBIO Diagnostics, 24 Av Joannes Masset, 69009 Lyon, France, hereby confirm that we have installed a quality management system according to the harmonized standard NF EN ISO 13485:2016. Our quality management system has been certified for compliance with said standard by the LNE/GMED (Certification no. 9742 rev. 12, valid until 20 July 2027).

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. 10, valid until 26 May 2025 and additional document 38916).

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.

The products marketed by LDBIO Diagnostics benefit from the transition period between Directive 98/79/EC and Regulation 2017/746. The conformity assessment is based on Annex IX (Regulation 2017/746) and the company is registered under the number FR-MF-000021697 on the EUDAMED database.

Lyon, le 24/07/2024

LDBIO DIAGNOSTICS  
Dr Denis LIMONNE  
Président, responsable qualité

## Attachment 1: Products List

| <u>Dénominations</u>  | <u>Références</u>                         | <u>Classification</u>                   |
|-----------------------|---|---|
| TOXOPLASMA WB IgG-IgM | TOP-WB12GM, TOP-WB24GM, TOP-WB96GM        | Annexe II, Liste B (Directive 98/79/CE) |
| 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   | Annexe II, Liste B (Directive 98/79/CE) |
| ASPERGILLUS WB IgG    | ASP-WB12G, ASP-WB24G, ASP- WB96G          |   |
| CHAGAS WB IgG         | CHA-WB12G, CHA-WB24G, CHA- WB96G          |   |
| LDBIO TOXO II IgM     | T2M-12M, T2M-24M, T2M-96M                 | Annexe II, Liste B (Directive 98/79/CE) |

|   |                                 |   |
|---|---------------------------------|---|
| A.FUMIGATUS WB IgE                          | AFU-WB12E, AFU-WB24E, AFU-WB96E |   |
| PEO WB IgG<br>(Bird breeder's disease)      | PEO-WB12G, PEO-WB24G, PEO-WB96G |   |
| SCHISTOSOMA ICT IgG-IgM                     | BILZ Ab ICT20, BILZ Ab ICT100   |   |
| TOXOPLASMA ICT IgG-IgM                      | TOXO Ab ICT20, TOXO Ab ICT100   | Annexe II, Liste B (Directive 98/79/CE) |
| ASPERGILLUS ICT IgG-IgM                     | ASPG Ab ICT20, ASPG Ab ICT100   |   |
| PEO ICT IgG-IgM<br>(Bird breeder's disease) | MPEO Ab ICT20, MPEO Ab ICT100   |   |
| CONJUGUE ANTI-IgG                           | WB-IG30, WB-IG60                | Annexe II, Liste B (Directive 98/79/CE) |
| CONJUGUE ANTI-IgM                           | WB-IM30, WB-IM60                | Annexe II, Liste B (Directive 98/79/CE) |
| CONJUGUE ANTI-IgA                           | WB-IA30, WB-IA60                | Annexe II, Liste B (Directive 98/79/CE) |
| CONJUGUE ANTI-IgE                           | WB-IE30, WB-IE60                |   |
| SUBSTRAT NBT-BCIP                           | WB-SA30, WB-SA125               | Annexe II, Liste B (Directive 98/79/CE) |
| DILUANT ECHANTILLON                         | WB-DE30, WB-DE125               | Annexe II, Liste B (Directive 98/79/CE) |
| LAVAGE CONCENTRE                            | WB-LC60, WB-LC250               | Annexe II, Liste B (Directive 98/79/CE) |