



EC DECLARATION OF CONFORMITY

Apacor Limited declares that the devices listed below conform to the relevant provisions of the EC Council Directive In Vitro Diagnostic Devices Directive 98/79/EC dated 27 October 1998. This compliance has been properly documented using checklist created from Annex III excluding point 6 of the Directive, linked to all supporting Technical Documentation.

Apacor Limited has a Quality Management System in place, which complies with ISO 13485 (Certificate Number GB18/873854) regulations and agrees to develop, implement and maintain the Quality Management System to ensure continued adequacy and efficacy.

| PRODUCT DESCRIPTION | PRODUCT CODE | EDMS CODE | CATEGORY |
|---|--------------|-----------|--------------------------------------|
| FORMALIN 10% | 1460 | 13070105 | Fixing Reagents (Histology/Cytology) |
| SODIUM-ACETATE ACETIC ACID FORMALIN (SAF) | 1461 | 13070105 | Fixing Reagents (Histology/Cytology) |
| MERTHIOLATE IODINE FORMALIN (MIF) | 1465 | 13070105 | Fixing Reagents (Histology/Cytology) |
| TRITON X - 100 SOLUTION | 1472 | 14050101 | Parasitology Extraction Reagents |
| ETHYL ACETATE | 1473 | 14050101 | Parasitology Extraction Reagents |
| FIELD'S STAIN - SOLUTION A | 1482 | 14050102 | Parasitology Stains |
| FIELD'S STAIN - SOLUTION B | 1483 | 14050102 | Parasitology Stains |
| GIEMSA STAIN – RAPID | 1484 | 14050102 | Parasitology Stains |
| LUGOL'S IODINE - AQUEOUS | 1486 | 14050102 | Parasitology Stains |
| IRON HAEMATOXYLIN - SOLUTION A | 1487 | 14050102 | Parasitology Stains |
| IRON HAEMATOXYLIN - SOLUTION B | 1488 | 14050102 | Parasitology Stains |
| TRICHROME FOR MICROSPORIDIA | 1489 | 14050102 | Parasitology Stains |
| TRICHROME FOR PROTOZOA | 1490 | 14050102 | Parasitology Stains |
| CARBOL FUCHSIN (GRAM) | 1495 | 14050102 | Parasitology Stains |
| MALACHITE GREEN | 1501 | 14050102 | Parasitology Stains |
| MODIFIED Z/N STAIN PACK (COLD KINYOUN) | 1503 | 14050102 | Parasitology Stains |

This Declaration of Conformity is signed below, certifying these requirements have been met.

Janet MacKenzie
General Manager
15 September 2018