



## 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 GB15/92533) and ISO 9001 (Certificate Number GB96/8685) 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

7 September 2016