



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 |
|-------------------------------|--------------|-----------|-------------------|
| CARESTART™ MALARIA PAN/PF | 1630 | 15700501 | Parasitology RT |
| H. PYLORI AG | 1632 | 15700102 | Bacteriology RT |
| LEISHMANIA DIPSTICK | 1601 | 15051005 | Misc Parasitology |
| FAECAL OCCULT BLOOD CARTRIDGE | 1642 | 11700301 | Faeces Tests RT |

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


Janet MacKenzie
General Manager

7 September 2016