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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.

RAPYDTEST®	PRODUCT CODE	EDMS CODE	CATEGORY
H. PYLORI AG	1632	15700102	Bacteriology RT
LEISHMANIA DIPSTICK	1601	15051005	Misc Parasitology
ROTAVIRUS/ADENOVIRUS CARTRIDGE	1640	15048006	Other Virology Antigen/Antibody Detection
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
15 September 2018

Apacor Limited, Unit 5 Sapphire Centre, Fishponds Road, Wokingham, RG41 2QL, England