



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
MIDI PARASEP	145000, 145300, 145400, 145500, 145501, 145650, 145750, 249200	15051090	Other Parasitology
MIDI PARASEP SF	149900, 149910, 149920, 149931, 149932, 149650, 149750, 249300	15051090	Other Parasitology
MINI PARASEP	146000, 146200, 146300, 146400, 146500, 146501, 146650, 146750, 248200	15051090	Other Parasitology
MINI PARASEP SF	148800, 148900, 148910, 148920, 148931, 148932, 148935, 148980, 148650, 148750, 248930, 108000, 180880, 108810, 108900, 108910, 108920, 108931, 108932, 108935	15051090	Other Parasitology
MAXI PARASEP	147001	15051090	Other Parasitology
30ML TRANSPORT VIALS	148998, 249400, 249420	15051090	Other Parasitology
CLEAN VIAL	149970	15051090	Other Parasitology

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