



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
CEROCON	06101006	11700290	Other Urine Testing
URICON	1259	11700290	Other Urine Testing
URIPREP SEDIMENTATION TUBES	RS0215	11700290	Other Urine Testing

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

Janet MacKenzie
General Manager

7 September 2016