DECLARATION OF CONFORMITY

MANUFACTURER:
Abaxis, Incorporated
3240 Whipple Road
Union City, CA 94587 USA

EUROPEAN REPRESENTATIVE:
Achim Henkel
Abaxis Europe, GmbH
Peka Park; T9
Otto-Hesse-Str. 19
D-64293 Darmstadt

PRODUCT: *VetScan HM5 Hematology System*

FOR VETERINARY USE ONLY

CONFORMITY ASSESSMENT ROUTE: *Article 3, Annex 1 and Annex III of the In Vitro Diagnostic Medical Device Directive, 98/79/EC of the European Parliament and of the Council of 27 October 1998*

We herewith declare that the above mentioned product meets the provisions of the *Council Directive 98/79/EC* for *in vitro diagnostic medical devices.* All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED:

ISO 13485	2003	Medical Devices – Quality Management Systems– Requirements for Regulatory Purposes
ISO 14971	2007	Medical Devices – Application of Risk Management to Medical Devices
ISO 15223	2000	Medical Devices – Symbols to Be Used with Medical Device Labels, Labeling and Information to Be Supplied
EN 980	2008	Symbols for Use in the Labelling of Medical Devices
21 CFR – PART 820	2010	Code of Federal Regulations – Quality System Regulation – cGMP for Medical Devices
9 CFR - PART114	2010	Code of Federal Regulations – Production Requirements for Biological Products
IEC/EN 61010-1	2010	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 1; General Requirements
IEC/EN 61010-2-010	2003	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 2-010: Particular Requirements for Laboratory Equipment for the Heating of Material
IEC/EN 61010-2-020	2006	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 2-020: Particular Requirements for Laboratory Centrifuges
IEC/EN 61010-2-081	2009	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 2-081: Particular Requirements for Automatic and Semi-Automatic Laboratory Equipment for Analysis and Other Purposes
IEC/EN 61010-2-101	2002	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 2-101: Particular Requirements for *In Vitro* Diagnostic (IVD) Medical Equipment
EN 61326-1	2006	Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements
EN 61326-2-6	2006	Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements - Part 2-6: Particular Requirements - *In Vitro* Diagnostic (IVD) Medical Equipment
JIS C 1010-1	2005	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements

Place and date of issue: Union City, CA USA. 30 January, 2012

Name and signature or equivalent marking of authorized person
Amrita Sethi, Senior Director of Regulatory Affairs, Quality Assurance and EH&S, Abaxis, Inc.