

## Declaration of Conformity

We, Abaxis, Incorporated  
3240 Whipple Road  
Union City, CA 94587  
U.S.A.

declare under our sole responsibility that the *In Vitro* diagnostic product,

### **Piccolo Xpress™ Chemistry System VetScan VS2® Chemistry System**

was produced in accordance with the procedures in Article 3, Annex I 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 and the Canadian Medical Devices Regulations (F-27-SOR/98-282).

The Piccolo Xpress™ blood chemistry analysis system is CE-Marked as a class I device and categorized as class II under the Canadian Medical Devices Regulations.

We declare under our sole responsibility that the system is in conformance with the following standards:

ISO 13485	2003	MEDICAL DEVICES – QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS FOR REGULATORY PURPOSES
ISO 14971	2000	APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES
ISO 14971	2003	APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES – AMENDMENT 1, RATIONAL FOR REQUIREMENTS
ISO 15223	2000	MEDICAL DEVICES – SYMBOLS TO BE USED WITH MEDICAL DEVICE LABELS, LABELING AND INFORMATION TO BE SUPPLIED
21 CFR - Parts 820	1997	CODE OF FEDERAL REGULATIONS – QUALITY SYSTEM REGULATION – CGMP FOR MEDICAL DEVICES
IEC/EN 61010-1	2001	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE PART 1: GENERAL REQUIREMENTS (SECOND EDITION)
IEC/EN 61010-2-010	2003	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE PART 2: PARTICULAR REQUIREMENTS FOR LABORATORY EQUIPMENT FOR THE HEATING OF MATERIALS
IEC/EN 61010-2-020	1990 & AM 1: 1996	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE PART 2: PARTICULAR REQUIREMENTS FOR LABORATORY CENTRIFUGES
IEC/EN 61010-2-081	2001	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: PARTICULAR REQUIREMENTS FOR IN VITRO DIAGNOSTIC (IVD) MEDICAL EQUIPMENT
EN 61326	1997 & AM 1: 1998; AM 2: 2001; AM 3: 2003	ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE – EMC REQUIREMENTS – PART 1: GENERAL REQUIREMENTS FOR A CLASS A DEVICE
JIS C 1010-1		JAPANESE INDUSTRIAL STANDARD: GENERAL REQUIREMENTS FOR SAFETY OF ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE

The technical file is maintained at:

**Abaxis, Incorporated  
3240 Whipple Road  
Union City, CA 94587**

A copy is maintained at:

**Abaxis European Office  
Otto-Hesse-Strasse 19  
T9, 3. OG Ost  
D-64293 Darmstadt  
Germany**

Union City, CA, USA

January 25, 2008

Place and date of issue

Name and signature or equivalent marking of authorized person

  
Paul Bailey, Quality Assurance Director