



**DECLARATION OF CONFORMITY**

**MANUFACTURER:**

Abaxis, Inc.  
3240 Whipple Road  
Union City, CA 94587, USA

**AUTHORIZED EUROPEAN UNION REPRESENTATIVE:**

Achim Henkel  
ABAXIS Europe, GmbH  
Bunsenstr. 9-11  
64347 Griesheim, Germany

**THE DIRECTIVES COVERED BY THIS DECLARATION:**

In Vitro Diagnostic Medical Devices Directive (IVDD) 98/79/EC

**THE PRODUCTS COVERED BY THIS DECLARATION:** See Attachment B, List of Products

**CLASSIFICATION:** Other (non-Annex II List A or List B)

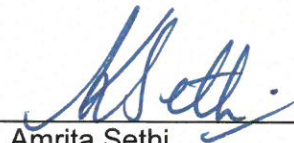
Self-certified IVD

**THE BASIS ON WHICH CONFORMITY IS BEING DECLARED**

Article 3, Annex I and Annex III excluding Section 6 of the In Vitro Diagnostic Medical Devices 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, as transposed into each member state legislation. See Attachment A for all Standards Applied. All supporting documentation is retained at the premises of the manufacturer.

**SIGNATURE:**

  
Amrita Sethi

VP Regulatory Affairs & Quality System Compliance

**DATE:** 28 November 2018



## DECLARATION OF CONFORMITY

### Attachment A: Standards Applied

Standard	Title
EN ISO 13485:2016	Medical devices-Quality Management Systems- Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices-application of risk management to medical devices
ISO 15223-1:2016	Medical Devices – Symbols to Be Used with Medical Device Labels, Labeling and Information to Be Supplied
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
EN 62304:2006	Medical Device Software: Software Life Cycle Processes
EN 13612:2002	Performance Evaluation of In Vitro Diagnostic Medical Devices
EN 62366:2008	Application of Usability Engineering to Medical Devices
EN ISO 17511:2003	Metrological Traceability of Values Assigned to Calibrators and Control Materials
EN ISO 18113-2:2011	Information Supplied by the Manufacturer with In Vitro Diagnostic Medical Devices - Reagents
EN ISO 18113-3:2011	Information Supplied By the Manufacturer with In Vitro Diagnostic Medical Devices - Instruments
EN ISO 23640:2013	Evaluation of Stability of In Vitro Diagnostic Reagents



## DECLARATION OF CONFORMITY

### Attachment B: List of Products

Piccolo Xpress® chemistry analysis System:

Part Number	Description
1100-0000E	Piccolo Xpress® chemistry analyzer, Europe
400-0003	PICCOLO® Liver Panel Plus
400-0006	PICCOLO® General Chemistry 6
400-0022	PICCOLO® Electrolyte Panel
400-0023	PICCOLO® MetLyte 8 Panel
400-0024	PICCOLO® Basic Metabolic Panel
400-0025	PICCOLO® Lipid Panel
400-0026	PICCOLO® Hepatic Function Panel
400-0027	PICCOLO® Renal Function Panel
400-0028	PICCOLO® Comprehensive Metabolic Panel
400-0029	PICCOLO® General Chemistry 13
400-0030	PICCOLO® Lipid Panel Plus
400-0031	PICCOLO® Basic Metabolic Panel Plus
400-0033	PICCOLO® Kidney Check
400-0034	PICCOLO® MetLyte Plus CRP
400-0035	PICCOLO® BioChemistry Panel Plus
400-0037	PICCOLO® Metlac 12 Panel
400-0041	PICCOLO® AmLyte 13