Declaration of Conformity

Legal Manufacturer
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268 USA

Place of Manufacture
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268 USA

EC Authorized Representative
Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
30175 Hannover
Germany

Notified Body (under 0197 to the EC Commission)
TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany

Products and Classification
See Attachment 1

Product Category
In Vitro Medical Devices

Conformity Assessment Routes
In Vitro Diagnostic Medical Device Directive 98/79/EC
Annex IV – Full Quality Assurance System & Annex III (excluding section 6)

Standards Applied
See Attachment 2

Polymer Technology Systems Inc. declares that the products listed meet the applicable requirements of the European *in vitro* Diagnostic Medical Devices Directive 98/79/EC.

Signature: Heidi Strunk Date: 6/23/2015

Heidi H. Strunk, RAC
Senior Director, Regulatory Affairs

Attachment 1 – PTS Declaration of Conformity – CardioChek Products

Catalog Number	Product Name	Classification		
		Annex II List B	Self-Test	"Other" IVD
	Analyzers			
1708	CardioChek PA Analyzer	•	•	•
1709	CardioChek Analyzer	•	•	•
2700	CardioChek Plus Analyzer			•
	Single Analyte Test Strips			
1713	PTS PANELS Glucose Test Strips (25 count)	•		•
1711	PTS PANELS Cholesterol Test Strips (25 count)		•	•
1712	PTS PANELS Cholesterol Test Strips (6 count)		•	•
1790	PTS PANELS Cholesterol Test Strips (3 count)		•	•
1714	PTS PANELS HDL Cholesterol Test Strips (25 count)		•	•
1715	PTS PANELS HDL Cholesterol Test Strips (6 count)		•	•
1788	PTS PANELS HDL Cholesterol Test Strips (3 count)		•	•
1716	PTS PANELS Triglycerides Test Strips (25 count)		•	•
1717	PTS PANELS Triglycerides Test Strips (6 count)		•	•
1789	PTS PANELS Triglycerides Test Strips (3 count)		•	•
1718	PTS PANELS Ketones Test Strips (25 count)		•	•
1719	PTS PANELS Ketones Test Strips (6 count)		•	•
1720	PTS PANELS Creatinine Test Strips (25 count)			•
2713	PTS PANELS eGLU Test Strips (50 count)			•
	Multi-Analyte Test Strips			
1710	PTS PANELS Lipid Panel Test Strips (15 count)		•	•
2400	PTS PANELS Metabolic Chemistry Panel Test Strips (15 count)	•		•
2412	PTS PANELS CHOL+HDL+GLU Panel Test Strips (15 count)	•		•
1765	PTS PANELS CHOL+GLU Test Strips (25 count)	•		•
1821	PTS PANELS CHOL+HDL Test Strips (25 count)		•	•
	Controls			
721	PTS PANELS Multi-Chemistry Controls (includes glucose, cholesterol, triglycerides and ketone)	•		•
722	PTS PANELS HDL Cholesterol Controls		•	•
860	ChekMate Strips			•
	Software and Accessories			
995	CardioChek Link			•
796	CardioChek Link cable (USB)			•
N/A	PTS Wellness Portal			•
	Capillary Blood Transfer Tubes			
2863	PTS Diagnostics Capillary Tubes (15 µL)			•
2864	PTS Diagnostics Capillary Tubes (20 µL)			•
2865	PTS Diagnostics Capillary Tubes (30 µL)			•
2866	PTS Diagnostics Capillary Tubes (40 µL)			•
2134	PTS Diagnostics Capillary Tubes (50 µL)			•

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Attachment 2

	Harmonized Standards
1	**In Vitro Diagnostics Directive**: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (1998-12-07 OJ No L 331/1)
2	**EN 980:2008:** Graphical symbols for use in the labelling of medical devices
3	**EN ISO 13485:2012/AC:2012** Medical devices - Quality management systems - Requirements for regulatory purposes
4	**EN 13612:2002:** Performance evaluation of in vitro diagnostic medical devices EN ISO 13612:2002/AC:2009
5	**EN 13640:2002:** Stability testing of in vitro diagnostic reagents
6	**EN ISO 14971:2012:** Medical devices - Application of risk management to medical devices (ISO 14971:2007, corrected version 2007-10-01)
7	**EN ISO 15197:2003:** In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus EN ISO 15197:2003/AC:2005
8	**EN ISO 18113-1:2011**: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
9	**EN ISO 18113-2:2011**: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
10	**EN ISO 18113-3:2011**: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)
11	**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 Reference document: IEC 61010-2-101:2002 (Modified)
12	**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 Reference document: IEC 61326-2-6:2005
13	**EN 62304:2006:** Medical device software - Software life-cycle processes Reference document: IEC 62304:2006, EN ISO 62304:2006/AC:2008
14	**EN 62366:2008:** Medical devices - Application of usability engineering to medical devices Reference document: IEC 62366:2007
	Standards Applied for Self-Testing Devices
15	**EN 13532:2002:** General requirements for in vitro diagnostic medical devices for self-testing
16	**EN ISO 18113-4:2011**: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)
17	**EN ISO 18113-5:2011**: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2009)