

Declaration of Conformity

Legal Manufacturer:

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

Place of Manufacture:

Polymer Technology Systems, Inc.
510 Oakmead Parkway
Sunnyvale, CA 94085 USA

EC Authorized Representative:

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

Notified Body / EC Certificate Number:

Not Applicable

Product:

A1CNow+

Product Category:

Glycated hemoglobin analysis system

Classification:

Directive 98/79/EC, Annex III

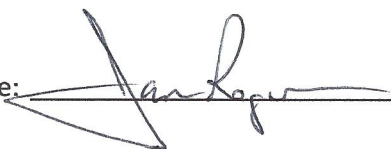
Conformity Assessment Route: Article 9, section 1, "other" IVD, according to Directive 98/79/EC

Standards Applied:

See Attachment

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

Signature: _____



Date: _____

02 December 2014

Jack Rogers
Director of Regulatory Affairs

Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268 USA
1-317-870-5610

Attachment – PTS Declaration of Conformity – A1CNow+

Harmonized Standards	
1	EN 980:2008: Graphical symbols for use in the labelling of medical devices
2	EN ISO 13485:2012/AC:2012 Medical devices - Quality management systems - Requirements for regulatory purposes
3	EN 13612:2002: Performance evaluation of in vitro diagnostic medical devices EN ISO 13612:2002/AC:2009
4	EN 13640:2002: Stability testing of in vitro diagnostic reagents
5	EN ISO 14971:2012: Medical devices - Application of risk management to medical devices (ISO 14971:2007, corrected version 2007-10-01)
6	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)
7	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)
8	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)
9	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)
10	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
11	EN 62304:2006: Medical device software - Software life-cycle processes Reference document: IEC 62304:2006, EN ISO 62304:2006/AC:2008
12	EN 62366:2008: Medical devices - Application of usability engineering to medical devices Reference document: IEC 62366:2007