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

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

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