Declaration of Conformity

AGILITY® Automated ELISA System

	Name and Address of Manufacturer	DYNEX Technologies, Inc. 14340 Sullyfield Circle Chantilly, VA 20151, USA
EC REP	Authorized European Representative	Acorn Regulatory Consultancy Services Limited Knockmorris, Cahir, Co. Tipperary, E21 R766 Ireland
UK REP	Authorized UK Representative	DYNEX Technologies Inc. Carmichael House, The Green, Inkberrow, Worcestershire, WR7 4DZ, UK

Conformity

Dynex Technologies Inc. confirms that the Agility fulfils the applicable obligations imposed by sections 1 to 5 of Annex III and verifies that the device meets the provisions of the In Vitro Diagnostic Medical Devices Directive 98/79/EC. The GMDN Code for the listed product is 56676.

REF	Name	UDI	Classification	GHTF Classification
67000	Agility Automated ELISA System	5060456180058	General IVD	Class A
67800-xxx*	Software for Agility	5060456180539	Accessory of a General IVD	Class A
67920	Reagent tips	5060456180089	Accessory of a General IVD	Class A
67910	Sample tips	5060456180072	Accessory of a General IVD	Class A

*Represent software version number

Standards Applied

Safety & EMC:

- UL 61010-2-10 3rd Ed. 2015-01-15 UL Standard for Safety Electrical Equipment for Measurement**,** Control, and Laboratory Use; Part 1: General Requirements
- EN 61010-2-101:2017- Safety requirement for electrical equipment for measurement, control, and laboratory use- Part 2: - Particular requirements for in vitro diagnostic (IVD) medical equipment.
- UL 61010-2-101 2nd Ed. 2015-08-14 UL Standard | Safety requirements for electrical equipment for measurement, control and laboratory use
- IEC 60825-1 Safety of laser products - Part 1: Equipment classification and requirements
- EN 61326-2-6:2013 (IEC 61326-2-6:2012) Electrical equipment for measurement, control and laboratory use - EMC requirements Part 2-6: Particular requirements - IVD medical equipment, using common technical requirements of EN 61326-1:2013
    - Radiated RF immunity 2 GHz to 2.7 GHz
    - Voltage dips and short interruptions immunity
- EN 61326-1:2006 Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General Requirements. With CFR 47, Part 15 Subpart B and ICES-003-4: 2004 for a Class A Device.
- CAN/CSA-C22.2 No. 61010-2-010:2015 CAS Standard Particular Requirements for Laboratory Equipment for the Heating of Materials
- CAN/CSA-C22.2 No. 61010-2-101:15 CAS standard Particular requirements for IVD medical equipment
- CAN/CSA-C22.2 No. 61010-1-12 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements-Tri-national standard, with UL 61010-1 and ANSI/ISA-61010-1 (82.02.01)

Other Standards:

- Statutory Instruments 2002 No.618 Consumer Protection. The Medical Device Regulations.
- ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- CEN EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
- EN ISO 18113-3:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)
- EN 62304: 2006 Medical device software - Software life-cycle processes
- EN 62366:2008 Medical devices – Application of usability engineering to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- 21 CFR Part 801 Labeling Subpart A; Part 820 Quality System Regulation; Part 822 Postmarket Surveillance
- EN ISO 15193:2009 In vitro diagnostic medical devices -- Measurement of quantities in samples of biological origin -- Requirements for content and presentation of reference measurement procedures
- EN 13975:2003 Sampling procedures used for acceptance testing of IVD medical devices. Statistical aspects

Authorized Signatory:

Candice Prowse
Director of Quality Assurance & Regulatory Affairs
Dynex Technologies Inc. Chantilly, VA

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AGILITY® CERTIFICATE OF COMPLIANCE TO RoHS 2

Dynex Technologies Inc. certifies that the AGILITY automated in ELISA analyzer to the best of our knowledge complies with the requirements of Directive 2011/65/EU, on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment.

The majority of Agility parts do not contain the following chemicals or they are in amounts below the allowable limits as shown in the table below.

Hazardous Substance:	Maximum Concentration:
Lead	1000 ppm
Mercury	1000 ppm
Cadmium	100 ppm
Hexavalent Chromium	1000 ppm
Polybrominated biphenyls	1000 ppm
Polybrominated diphenyl ethers (PBDE)	1000 ppm

The following parts use RoHS exemptions:

Part Number	Description	Exemption
426000900	Pinch Valve Small,	6C
31600015	Broaching Nut	6C
31600016	Stainless Steel Pc Board Fastener M2x0.4 Thread Size Broaching Nut	6C
31600017	Broaching Stud	6C
31600018	Spacer, M3 Thread 0.5mm Pitch 4mm Long Reelfast SMT	6C
31600019	Spacer, M2 Thread 0.4mm Pitch 2MM Long Reelfast SMT	6C
33000400	M0591-4-N-0 Spacer 4.3X8X2 N	6C
33000860	Standoff, M3 X 9mm Long, 8mm HEX, F/F, Nylon	6C
41500405	Filter 405nm	13(A) 13(B)
41500490	Filter 490nm	13(A) 13(B)
41500620	Filter 620nm	13(A) 13(B)
30300050	Screw, 5/16"-18 X 1.25" HEX Head, SS (Full Thread)	6B
419010000	Encoder-Increm HEDS-5500-H14	6B

6B Lead as an alloying element in aluminium containing up to 0.4% lead by weight. 6C Copper alloy containing up to 4% lead by weight. 13A Lead in white glasses used for optical applications 13B Cadmium and lead in filter glasses and glasses used for reflectance standards.

CHINA RoHS Directive Restrictive Substances Standard SJ/T11364-2014 Table:

	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr6)	Polybrominated Biphenyls (PBB)	Polybrominated Diphenyl Ethers (PBDE)
PCB Electronics	X	O	O	O	O	O
Harnesses	O	O	O	O	O	O
Chassis and casework	O	O	O	O	O	O
Mechanical assemblies	O	O	O	O	O	O
Sample Rack Scanner Laser line generator	X	O	O	O	O	O
Motherboard	X	O	O	O	O	O
Touchscreen	O	X	O	O	O	O
Accessories	O	O	O	O	O	O

O: indicates that this toxic or hazardous substance contained in all the homogeneous materials for this part, according to EIP-A, EIP-B, EIP-C is below the limit requirement in GB/T 26572.

X: indicates that this toxic or hazardous substance contained in all the homogeneous materials for this part, according to EIP-A, EIP-B, EIP-C is above the limit requirement in GB/T 26572.

Environment Friendly Use Period (EFUP) is 10 years.

Authorized Signatory:

Candice Prowse
Director of Quality Assurance & Regulatory Affairs
Dynex Technologies Inc. Chantilly, VA
Date : 2019-05-13