Declaration of Conformity

Agility® Automated ELISA System

	Name and Address of Manufacturer:	DYNEX Technologies, Inc. Sullyfield Circle Chantilly, VA 20151, USA
EC REP	Name and Address of the Authorized European Representative:	DYNEX Technologies, Inc. Yeoman Gate, Yeoman Way, Worthing, West Sussex BN13 3QZ, UK

Conformity
Dynex Technologies Inc. confirms that the Agility has fulfil 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

REF	Name	GMDN Code	Classification	GHTF Classification
67000	Agility Automated ELISA System	56676	General IVD	Class A
67800	Software for Agility		Accessory of a General IVD	Class A
67920	Reagent tips		Accessory of a General IVD	Class A
67910	Sample tips		Accessory of a General IVD	Class A

Standards Applied

- Statutory Instruments 2002 No.618 Consumer Protection
- EN 61010-2 -101- Safety requirement for electrical equipment for measurement, control, and laboratory use- Part 2: I 0 I - Particular requirements for in vitro diagnostic (IVD) medical equipment.
- Electromagnetic compatibility: EN 61326-1:2006 with CFR 47, Part 15 Subpart B and ICES-003-4: 2004 for a Class A Device
- EN 980:2008 Symbols for use in the labelling of medical devices
- EN ISO 13485:2003 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 (labelling) - 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 61326-2-6:2013 using common technical requirements of EN61326-1:2013
    - Radiated RF immunity 2 GHz to 2.7 GHz
    - Voltage dips and short interruptions immunity
- IEC 61010-2-010:2014 Ed. 3.0, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- IEC 61010-2-101 2015 Ed. 2.0 b:2002, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular ... in vitro diagnostic (IVD) medical equipment
- EN 61010-2-101 2017, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular ... in vitro diagnostic (IVD) medical equipment
- 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
- CAN/CAS-C22.2 No. 61010-2-010:15 CAS standard Particular Requirements for Laboratory Equipment for the Heating of Materials
- UL 61010-2-101 2rd Ed. 2015-08-14 UL Standard | Safety requirements for electrical equipment for measurement, control and laboratory use
- CAN/CAS-C22.2 No. 61010-2-101:15 CAS standard Particular ... in vitro diagnostic (IVD) medical equipment
- EN 61010-2-101 2017, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular ... in vitro diagnostic (IVD) medical equipment

Authorized Signatory:

C. Prowse.

Candice Prowse

Director of Quality Assurance & Regulatory Affairs

Signed at Dynex Technologies Inc. Chantilly, VA

On 2018-06-18

Document ref. No. DOC Agility CE

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 table 1.

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 a 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 aluminum 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

C. Prowse.

Candice Prowse

Director of Quality Assurance and Regulatory Affairs

2017-11-28