DYNEX TECHNOLOGIES	**Agility® Automated ELISA System and Accessories**
CONFIDENTIAL	**Declaration of Conformity**

	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. Second Floor, 3 Liverpool Gardens, Worthing, West Sussex, BN11 1TF United Kingdom
	EU Importer	DYNEX Technologies, GmbH Heerweg 15D, 73770 Denkendorf, Germany Phone: +49 (0) 711-900349-66 Fax: +49 (0) 711-900349-68

Name:	Agility
Registered Trade Name:	Agility® Automated ELISA System
SRN referred to in Article 28	US-MF-000014753
Address and Contact Details	DYNEX Technologies, Inc. 14340 Sullyfield Circle Chantilly, VA 20151 USA Phone: 800-288-2354
Basic UDI-DI	506045618AGILITYBB
Product Code	56676
Product Catalogue Number	67000
Intended Purpose	Agility is an automated Enzyme-Linked Immunosorbent Assay (ELISA) system with open functionality for processing immunochemistry assays.
Risk Classification	Class A per Rule 5 (a) and (b) set out in Annex VIII: (a) Products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for *in vitro*

	diagnostic procedures relating to a specific examination; (b) Instruments intended by the manufacturer specifically to be used for *in vitro* diagnostic procedures.
Accessories	

REF	Name	UDI-DI	Classification
67000	Agility® Automated ELISA System	5060456180058	Class A
67800-xxx*	Agility® Software	5060456180539	Class A
67920	Reagent tips	5060456180089	Class A
67910	Sample tips	5060456180072	Class A
62910	Deep-well strips (250/box)	5060456180614	Class A

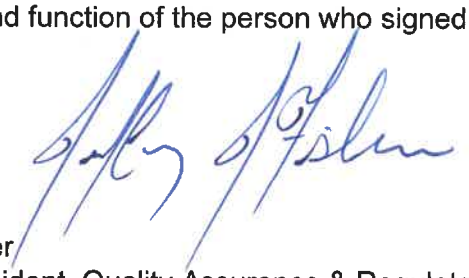
*Represents the software version number

The device conforms to the following regulations and standards	This Declaration has been written in accordance with IVDR 2017/746 Article 17 and Annex IV for In Vitro Diagnostic Devices. DYNEX Technologies, Inc. confirms that the Agility adheres to Council Regulation (EU) IVDR 2017/746 for In Vitro Diagnostic Devices. **Safety & EMC**: - IEC 61010-1 Ed.3.1 b:2017- Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General Requirements • Electromagnetic compatibility - BS EN IEC 61326-1:2021 with CFR 47, Part 15 Subpart B Unintentional Radiators and ICES-003-4: 2004 Digital Apparatus • BS EN IEC 61326-1:2021 Electrical equipment for measurement, control and laboratory use. EMC requirements- Part 1: General requirements • IEC 60825-1 Ed.3.0 b:2014 Safety of laser products - Part 1. Equipment classification and requirements • EN 61326-2-6:2021 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirement - In vitro diagnostic (IVD) medical equipment. • CAN/CSA C22.2 No. 61010-1:2012 (R2022) Ed.3 Safety Requirements for Electrical Equipment for

	Measurement, Control, And Laboratory Use - Part 1: General Requirements. • CAN/CSA C22.2 No. 61010-2-010:2019 Ed.4 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-010: Particular Requirements For Laboratory Equipment For The Heating of Materials. • CAN/CSA C22.2 No. 61010-2-101-2019 Ed.3 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment. **Other Standards**: • UK Statutory Instrument 2002 No.618 Consumer Protection • ISO 15223:2021 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 14971:2019+A11:2021 Medical Devices - Application of risk management to medical devices • EN ISO 18113-3:2011 In vitro diagnostic medical devices - Information supplied by the manufactures (labelling) - Part3: In vitro diagnostic instruments for professional use • EN 62304:2006+A1:2015 Medical device software - Software life-cycle processes • EN 62366-1:2015+A1:2020 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 General Labeling Provisions; Part 820 Quality System Regulation; Part 822 Post Market Surveillance • Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC
Common Technical Specification	Not applicable
Notified Body	Not required
Conformity Assessment Procedure	Self Certified
CE Certificate	Not applicable for Class A

This Declaration of Conformity is issued under the sole responsibility of the manufacturer, DYNEX Technologies, Inc.

Name and function of the person who signed:



Jeff Fisher
Vice President, Quality Assurance & Regulatory Affairs

Place and date of issue of the declaration: 2023-09-05

DYNEX Technologies, Inc.
14340 Sullyfield Circle
Chantilly, VA 20151 USA

Agility® CERTIFICATE OF COMPLIANCE TO RoHS 3

DYNEX Technologies, Inc. certifies that the Agility automated ELISA system, to the best of our knowledge, complies with the requirements of Directive 2011/65/EU, as amended by EU 2015/863, 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 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
Bis(2-ethylhexyl) phthalate (DEHP)	1000 ppm
Butyl benzyl phthalate (BBP)	1000 ppm
Dibutyl phthalate (DBP)	1000 ppm
Di isobutyl phthalate (DIBP)	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

Part Number	Description	Exemption
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

	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:

Jeff Fisher
Vice President, Quality Assurance & Regulatory Affairs
DYNEX Technologies, Inc. Chantilly, VA 20151 USA

Date: 2023-09-05