Declaration of Conformity

DSX® 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 DSX 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
65100	DSX Automated ELISA System ambient	56676	General IVD	Class A
65200	DSX Automated ELISA System with 2 incubators		General IVD	Class A
65400	DSX Automated ELISA System with 4 incubators		General IVD	Class A
65078-625	DSX-Revelation Software for DSX™		Accessory of a General IVD	Class A

Standards Applied

Safety & EMC

- Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use - Part 1: General Requirements [UL 61010-1:2012 Ed.3 +R:15Jul2015]
- Safety Requirements For Electrical Equipment For Measurement, Control And Laboratory Use - Part 2-010: Particular Requirements For Laboratory Equipment For The Heating Of Materials [UL 61010-2-010:2015 Ed.3]
- UL 61010-2-101 Issued: 2015/08/14 Ed: 2 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-101: 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
- IEC 61326-1Issued: 2012/07/10 Ed: 2 Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements
- 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
- CSA C22.2#61010-2-081 Issued:2004/07/01 Ed:1 (R2009) Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-081: Particular requirements for automatic and semiautomatic laboratory equipment for analysis and other purposes
- Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment [CSA C22.2#61010-2-101:2015 Ed.2]
- Safety Requirements For Electrical Equipment For Measurement, Control And Laboratory Use - Part 2-010: Particular Requirements For Laboratory Equipment For The Heating Of Materials [CSA C22.2#61010-2-010:2015 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 [CSA C22.2#61010-2-101:2015 Ed.2]

Other Standards

- Statutory Instruments 2002 No.618 Consumer Protection
- 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

Authorized Signatory:

Candice Prowse
Director of Quality Assurance & Regulatory Affairs
Signed at Dynex Technologies Inc. Chantilly, VA
On 2018-05-23

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DSX® CERTIFICATE OF COMPLIANCE TO RoHS 2

Dynex Technologies Inc. certifies that the DSX 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 DSX 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
23001915	MF55D1215F;RES 12.1M 1%	6C
24500550	ASSAY FIBER OPTICS	13A 13B
528300700	JEDEC XYZ1V1.JED U3	6B
528300800	PMCD160212 FITTING 1/8 BARB PP	6B
528300900	SML-LX1206GC-TR LED GREEN	6B
528300901	EXTRUSION 80 X 40 CROSS MEMBER	6B
528301000	5710-510-10 SPACER BEARING SS	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)
Reader module	X	O	X	O	O	O
Washer Module	O	O	O	O	O	O
Main Chassis	O	O	O	O	O	O
Casework	O	O	O	O	O	O
Transport Arms	X	O	O	O	O	O
Incubator Module	O	O	O	O	O	O
Pipette Module	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

C. Prowse.

Candice Prowse

Director of Quality Assurance and Regulatory Affairs

2016-10-25