Declaration of Conformity

DSX® 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 DSX 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 products is 56676.

REF	Name	UDI	Classification	GHTF Classification
65100	DSX Automated ELISA System ambient	5060456180287	General IVD	Class A
65200	DSX Automated ELISA System with 2 incubators	5060456180157	General IVD	Class A
65300	DSX Automated ELISA System with 2 incubators w/ Sample ID	5060456180218	General IVD	Class A
65400	DSX Automated ELISA System with 4 incubators	5060456180010	General IVD	Class A
65500	DSX Automated ELISA System with 4 incubators w/ Sample ID	5060456180300	General IVD	Class A
65078-xxx*	REVELATION DSX® Software	5060456180546	Accessory of a General IVD	Class A
65920	Reagent tips (432/box)	5060456180034	Accessory of a General IVD	Class A

* Represents the software version number

REF	Name	UDI	Classification	GHTF Classification
65910	Sample tips (432/box)	5060456180041	Accessory of a General IVD	Class A

Standards Applied

Safety & EMC

- IEC 61010-1:2010; AMD1:2016 Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use – Part 1: General Requirements [UL 61010-1:2012 Ed.3 +R:15Jul2015]
- IEC 61010-2-010:2014 Safety Requirements For Electrical Equipment For Measurement, Control And Laboratory Use - Part 2-010: Particular Requirements For Laboratory Equipment For The Heating Of Materials
- IEC 61010-101:2015 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
- IEC 61326-1 Issued: 2012/07/10 Ed: 2 Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements
- EN 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- CSA C22.2#61010-1:2012 Ed.3 Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use Part 1: General Requirements (R2017)
- CSA C22.2#61010-2-101:2015 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.

Other Standards

- Statutory Instruments 2002 No.618 Consumer Protection
- ISO 15223:2016 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 14971:2019 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 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
- Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC

Authorized Signatory:

Jeff Fisher
Vice President, Quality Assurance & Regulatory Affairs Manager
Dynex Technologies Inc. Chantilly, VA
Date: 2021-07-01

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DSX® CERTIFICATE OF COMPLIANCE TO RoHS 2

Dynex Technologies Inc. certifies that the DSX automated 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 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
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 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)
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

Authorized Signatory:

Jeff Fisher
Vice President, Quality Assurance & Regulatory Affairs
Dynex Technologies Inc. Chantilly, VA
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