DYNEX® TECHNOLOGIES	**DSX® 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:	DSX
Registered Trade Name:	DSX® 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	506045618DSXFQ
Product Code	56676
Product Catalogue Number	65400
Intended Purpose	DSX 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.

Variant & Accessories

REF	Name	UDI-DI	Classification
65100	DSX® Automated ELISA System - Ambient	5060456180287	Class A
65200	DSX® Automated ELISA System with 2 incubators	5060456180157	Class A
65300	DSX® Automated ELISA System with 2 incubators and sample ID	5060456180218	Class A
65400	DSX® Automated ELISA System with 4 incubators	5060456180010	Class A
65500	DSX® Automated ELISA System with 4 incubators and sample ID	5060456180300	Class A
65078-xxx*	REVELATION DSX® Software	5060456180546	Class A
65920	Reagent tips (432/box)	5060456180034	Class A
65910	Sample tips (432/box)	5060456180041	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 DSX adheres to Council Regulation (EU) IVDR 2017/746 for In Vitro Diagnostic Devices.

Safety & EMC:

- IEC 61010-1:2010/AMD1:2016 Amendment 1 - 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
- 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 Instruments 2002 No.618 Consumer Protection – The Medical Devices Regulations 2002
- ISO 15223-1:2021 Medical devices -- Symbols to be used with information to be supplied by the manufacturer - 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) – Part 3: 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

DSX® CERTIFICATE OF COMPLIANCE TO RoHS 3

DYNEX Technologies, Inc. certifies that the DSX 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 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
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
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

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)
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 20151 USA

Date : 2023-09-05