Declaration of Conformity

DS2® 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 DS2 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. The GMDN Code for the listed products is 56676.

REF	Name	UDI	Classification	GHTF Classification
62000	DS2 Automated ELISA System	5060456180317	General IVD	Class A
62010	DS2 Automated ELISA System with barcode scanner	5060456180003	General IVD	Class A
62800-xxx*	DS-Matrix® Software	5060456180553	Accessory of a General IVD	Class A
65920	Reagent tips (432/box)	5060456180034	Accessory of a General IVD	Class A
65910	Sample tips (432/box)	5060456180041	Accessory of a General IVD	Class A

* Represents the software version number

Standards Applied

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 - EN 61326-1:2006 with CFR 47, Part 15 Subpart B and ICES-003-4: 2004 for a Class A Device
- IEC 61326-1 Issued: 2012/07/10 Ed: 2 Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements
- IEC 60825-1 Safety of laser products - Part 1: Equipment classification and 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#61010-2-010:2015 Ed.3 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#61010-2-101:2015 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 Instrument 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 14971:2012 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 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

Authorized Signatory:

Candice Prowse
Director of Quality Assurance & Regulatory Affairs
Dynex Technologies Inc. Chantilly, VA
Date : 2019-05-13

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DS2 CERTIFICATE OF COMPLIANCE TO RoHS 2

Dynex Technologies Inc. certifies that the DS2 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 DS2 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 a RoHS exemptions:

Part Number	Description	Exemption
23500411	Lower Drive Block DS2	6C
23500421	Guide Shaft DS2	6C
23500510	Bearing Block DS2	6C
23500640	Insulation Plate DS2	6C
23500680	Incubator Door DS2	6C
23501570	Tip Rack Locking Plate DS2	6C
23501630	Cover Adjuster DS2	6C
24500550	Assay Fiber Optics AM	13(A) 13(B)
24900081	Purge Tray DS2	6C
24900140	Fiber Optics DS2	13(A) 13(B)
50800161	Motor Axis Drive Small DS2	6b
50800171	Motor Axis Drive Large DS2	6b
50800180	Motor Reader DS2	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

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