Declaration of Conformity

DS2® 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 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

REF	Name	GMDN Code	Classification	GHTF Classification
62000	DS2 Automated ELISA System	56676	General IVD	Class A
62010	DS2 Automated ELISA System with barcode scanner		General IVD	Class A
62800-134	DS2-Matrix Software		Accessory of a General IVD	Class A
65920	Reagent tips (432/box)		Accessory of a General IVD	Class A
65910	Sample tips (432/box)		Accessory of a General IVD	Class A

Standards Applied

- Statutory Instruments 2002 No.618 Consumer Protection
- EN 61010-2 -101- Safety requirement for electrical equipment for measurement, control, and laboratory use- Part 2: I 0 I - 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
- 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
- IEC 61326-1Issued: 2012/07/10 Ed: 2 Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements
- GB/T 18268.1-2010 Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 1:General requirements; GB/T 18268.26-2010 Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 26:Particular requirements -- In vitro diagnostic (IVD) medical equipment
- 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
- EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment 61010-2-101:2002
    - CISPR (11:2009)
    - Harmonics IEC 61000-3-2:2005 +A1:2008 +A2:2009
    - Flicker IEC 61000-3-3:2008
    - Electro-Static Discharge Immunity Test (IEC 61000-4-2:2008)
    - Radiated, Radio-Frequency, Electromagnetic Immunity (IEC 61000-4-3:2006 +A1:2007 +A2:2010)
    - Electrical Fast Transient/Burst Immunity Test (IEC 61000-4-4:2007)
    - Immunity to Surges (IEC 61000-4-5:2005)
    - Conducted, Radio-Frequency, Electromagnetic Immunity Test (IEC 61000-4-6:2008)
    - Power Frequency Magnetic Field Immunity Test (IEC 61000-4-8:2009)
    - Voltage Dips/Interruptions Immunity Test (IEC 61000-4-11:2004)

- UL 61010-1, Second Edition, 2004 Issued: 2008/10/28 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements; Revision 2005, Revision 2008
- IEC 61010-2-010: 2003, Second Edition Issued: 2003/06/18 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 61010-2-081: 2009, Edition 1.1 Issued: 2009/08/31 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

- IEC 61010-2-101: 2002, First Edition Issued: 2002/01/09 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#61010-1 Issued: 2004/07/12 Ed: 2 (R2009) Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements, with general instruction No. 1: 2008/10/28 - (R2009)
- CSA C22.2#61010-2-010 Issued:2004/07/01 Ed:2 (R2009) 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#61010-2-081 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
- CSA C22.2#61010-2-101 Issued:2004/07/01 Ed:1 (R2009) Safety requirements for electrical
- equipment for measurement, control and laboratory use Part 2-101: Particular requirements for Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Authorized Signatory:

Candice Prowse

Director of Quality Assurance & Regulatory Affairs

Signed at Dynex Technologies Inc. Chantilly, VA

On 2016-10-20

Document ref. No. DOC DS2

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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 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
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 OPTIC 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 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

2016-10-13