DYNEX TECHNOLOGIES	**DS2® 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. Unit B2 Yeoman Gate Yeoman Way, Worthing, BN13 3QZ

Name:	DS2
Registered Trade Name:	DS2 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 +1 703-631-7800, FAX 703-803-1441
Unique Identification Number Device Identifier (UDI-DI)	5060456180003
Product Code	56676
Product Catalogue Number	62010
Intended Purpose	DS2 is an automated Enzyme-Linked Immunosorbent Assay (ELISA) analyzer 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
62000	DS2 Automated ELISA System	5060456180317	Class A
62800-xx*	DS-Matrix® Software	5060456180553	Class A
65920	Reagent tips (432/box)	5060456180034	Class A
65910	Sample tips (432/box)	5060456180041	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 DS2 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 - EN 61326-1:2006 with CFR 47, Part 15 Subpart B and ICES-003-4: 2004 for aClass A Device
- IEC 6132&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 requirement - In vitro diagnostic (IVD) medical equipment.
- CSA C22.2#61010-1:2012 Ed.3 Safety Requirements For Electrical Equipment For Measures Control, And Laboratory Use Part 1: General Requirements (R-2017).
- 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#61010-2-101A15 Ed.2 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use -- Part 2: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment. **Other Standards**: • Statutory Instrument 2002 No.618 Consumer Protection • ISO 15223:2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to besupplied -- 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 manufactures (labelling) - Part3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009) • EN 62304:2006 Medical device software - Software life-cycle processes • EN 62360:2008 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 Post Market 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
Common Technical Specification	Not applicable
Notified Body	Not applicable
Conformity Assessment Procedure	Self Certified

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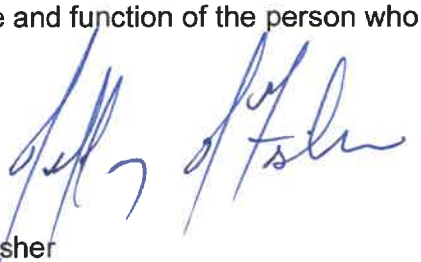
This Declaration of Conformity is issued under the sole responsibility of the manufacturer, DYNEX Technologies, Inc.

Name and function of the person who signed:



Jeff Fisher
Vice President of Quality Assurance and Regulatory Affairs

CE 2797

Place and date of issue of the declaration: 2022-06-27

DYNEX Technologies, Inc.
14340 Sullyfield Circle
Chantilly, VA 20151, USA.

DYNEX TECHNOLOGIES

DS2 CERTIFICATE OF COMPLIANCE TO RoHS 3

Dynex Technologies, Inc. certifies that the DS2 automated ELISA analyzer, 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 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
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 a RoHS exemption:

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 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.

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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

Date : 2022-06-27