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
	SRN: US-MF-000014753	
EU REP	Authorized European Representative	Acorn Regulatory Consultancy Services Limited Knockmorris, Cahir, Co. Tipperary, E21 R766 Ireland
	SRN: IE-AR-000000592	
UK REP	Authorized UK Representative:	DYNEX Technologies, Inc. Second Floor, 3 Liverpool Gardens, Worthing, West Sussex, BN11 1TF United Kingdom

Name:	DS2
Registered Trade Name:	DS2® Automated ELISA System
Product Catalogue Number	62010
Address and Contact Details:	DYNEX Technologies, Inc. 14340 Sullyfield Circle Chantilly, VA 20151 USA Phone: 800-288-2354
Basic UDI-DI	506045618DS2DE
GMDN Code	56676
EMDN Code	W0201020101
Intended Purpose	DS2 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
62010	DS2® Automated ELISA System with Barcode Scanner	5060456180003	Class A
62000	DS2® Automated ELISA System without Barcode Scanner	5060456180317	Class A
62800-xxx*	DS-Matrix® Software	5060456180690	Class A
50900021-XXX**	Dongle for Licensing of SW and Features	5060456182250	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
**Represents the enabled features

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 Medical Devices.

DYNEX Technologies, Inc. confirms that the DS2 adheres to Council Regulation (EU) IVDR 2017/746 for In Vitro Diagnostic Medical Devices.

Packaging Compliance - Regulation (EU) 2025/40 (PPWR)

According to EU 2025/40 Article 6 Recyclable packaging clause 11 part (c). The majority of the packaging used being in direct contact with the IVD; meaning the packaging is exempt from the EU 2025/40 Regulation. The elements of the packaging outside of the exemption are recyclable or within the thresholds/limits established within the regulation. Therefore packaging used is in compliance with EU 2025/40 PPWR.

Safety & EMC:

- IEC 61010-1 Ed.3.1 b:2017- 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
- BS EN 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 Instrument 2002 No.618 Consumer Protection
- ISO 15223-1:2021/ Amd1:2025 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+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:

Signed by:
Evan Rollins
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Dynex Technologies Inc. Corporate Seal 2004 DELAWARE

Evan Rollins
Vice President, Global Quality & Regulatory Affairs

Place and date of issue of the Declaration: 2026-07-31

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

DS2® CERTIFICATE OF COMPLIANCE TO RoHS 3

DYNEX Technologies, Inc. certifies that the DS2 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 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 (Pb)	0.1%
Mercury (Hg)	0.1%
Cadmium (Cd)	0.01%
Hexavalent chromium (Cr6+)	0.1%
Polybrominated Biphenyls (PBB)	0.1%
Polybrominated Diphenyl Ethers (PBDE)	0.1%
Bis(2-Ethylhexyl) phthalate (DEHP)	0.1%
Benzyl butyl phthalate (BBP)	0.1%
Dibutyl phthalate (DBP)	0.1%
Diisobutyl phthalate (DIBP)	0.1%

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

6(b) Lead as an alloying element in aluminum containing up to 0.4% lead by weight.
6(c) Copper Alloy containing up to 4% Lead by weight.
13(a) Lead in white glasses used for optical applications.
13(b) 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

Environment Friendly Use Period (EFUP) is 10 years.

Authorized Signatory:

Signed by:
Evan Rollins
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Dynex Technologies Inc. Corporate Seal 2004 DELAWARE

Evan Rollins
Vice President, Global Quality & Regulatory Affairs
DYNEX Technologies, Inc., Chantilly, VA 20151 USA

Date: 2026-07-31