Declaration of Conformity

DSX® 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
65100	DSX Automated ELISA System ambient	56676	General IVD	Class A
65200	DSX Automated ELISA System with 2 incubators		General IVD	Class A
65400	DSX Automated ELISA System with 4 incubators		General IVD	Class A
65078-625	DSX-Revelation Software for DSX™		Accessory of a General IVD	Class A

Standards Applied

- Statutory Instruments 2002 No.618 Consumer Protection
- ISO 13485:2003- Medical Devices - Quality management systems
- ISO 14971:2007- Medical Devices- Application of risk management to medical devices
- ISO 18113-1:2009 - In vitro diagnostic medical devices - Information supplied by manufacturer, (labeling) Terms, definitions, general requirements
- ISO 18113-3:2009 - In vitro diagnostic medical devices - Information supplied by manufacturer (labelling) In vitro diagnostic instruments for professional use.
- ISO 15223-1- Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied - Part I : General requirements
- 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.
- EN 61010-1:2001- Safety requirement for electrical equipment for measurement, control, and laboratory use -Part I : General requirements
- EN 61326-1:2006 -Electrical equipment for measurement, control and laboratory use- EMC
- requirements, Part I - General requirements
- EN 61010-2-081:2002 - Safety requirements for electrical equipment for measurement, control and laboratory use, Part 2-081 - Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
- Electromagnetic compatibility :EN 61326-1:2006 with CFR 47, Part 15 Subpart B and ICES-003-4: 2004 for a Class A Device

Authorized Signatory:

Candice Prowse

Director of Regulatory Affairs

Signed at Dynex Technologies Inc. Chantilly, VA

On 2015-11-30

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