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DECLARATION OF CONFORMITY

European Union *In Vitro* Diagnostic Directive 98/79/EC (IVDD)

Date of Issue:	September 28, 2016
Certificate Ref.:	These products are self-declared for compliance to Annex III of the IVDD. These products do not claim any analytes listed in Annex II List A or B.
Directive:	98/79/EC IVD Directive of 27 October 1998

Conforming Products:

Catalog Number	Product Description	EDMA Classification	GMDN Code
10011723	DRI® Ethyl Glucuronide Assay	12.09.02.07	60663
10011297	DRI® Ethyl Glucuronide Assay	12.09.02.07	60663
10011226	DRI® Ethyl Glucuronide Assay	12.09.02.07	60663
10015626	DRI® Ethyl Glucuronide Assay	12.09.02.07	60663
10011207	DRI® Ethyl Glucuronide Negative Calibrator (25 mL)	12.50.01.01	60666
10011208	DRI® Ethyl Glucuronide Calibrator 100 ng/mL (10 mL)	12.50.01.01	60666
10011210	DRI® Ethyl Glucuronide Calibrator 500 ng/mL (10 mL)	12.50.01.01	60666
10011212	DRI® Ethyl Glucuronide Calibrator 1000 ng/mL (10 mL)	12.50.01.01	60666
10011213	DRI® Ethyl Glucuronide Calibrator 2000 ng/mL (10 mL)	12.50.01.01	60666
10012135	DRI® Ethyl Glucuronide 375 ng/mL Control (25 mL)	12.50.01.02	60667
10012136	DRI® Ethyl Glucuronide 625 ng/mL Control (25 mL)	12.50.01.02	60667
10012137	DRI® Ethyl Glucuronide 750 ng/mL Control (25 mL)	12.50.01.02	60667
10012138	DRI® Ethyl Glucuronide 1250 ng/mL Control (25 mL)	12.50.01.02	60667

Manufacturer:	Microgenics Corporation – Thermo Fisher Scientific 46500 Kato Road, Fremont, CA 94538, USA
Authorized Representative:	B·R·A·H·M·S GmbH, Neuendorfstraße 25, 16761 Hennigsdorf, Germany
Notified Body:	TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nurnberg, Germany
Harmonized Standards Referenced:	• EN ISO 13485:2012 • EN ISO 14971:2012 • EN 13612:2002 • EN ISO 23640:2015 • EN 980:2008 • EN 13461:2002 • EN ISO 18113-1:2011 • EN ISO 18113-2:2011 • EN 62366:2008
Other regulations/ standards by which product is regulated:	• ANSI Z400.1:2010 • EU CLP - Regulation EC No 1272/2008 USA Food and Drug Administration (FDA) regulations: • 21 CFR Parts 820, Quality System Regulations

Microgenics Corporation's Quality Management System is certified to ISO 13485:2012 by TÜV Rheinland LGA Products GmbH. Certificate # SX 60105994 0001.

We hereby certify that as of the date of this declaration, the products described above conform with the provisions of Council Directive 98/79/EC IVD Directive of 27 October 1998 relating to *in-vitro* diagnostic devices. All supporting documentation is retained at Microgenics Corporation.

Signature: _____ Dated: 09.28.2016

Jeffrey J. Fisher, Director, Regulatory and Compliance

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