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DECLARATION OF CONFORMITY

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

Date of Issue:	25 March 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
0373852	QMS® Everolimus Immunoassay	12.08.06.90	60452
10015993	QMS® Everolimus Immunoassay (Indiko Kit)	12.08.06.90	60452
0373878	QMS® Everolimus Immunoassay Control Set	12.50.01.02	60456
0373860	QMS® Everolimus Immunoassay Calibrator Set	12.50.01.01	60455

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 13640:2002 ▪ EN ISO 18113-1:2011 ▪ EN ISO 18113-2:2011 ▪ EN 13641:2002 ▪ EN 62366:2008
Other regulations/ standards by which product is regulated:	USA Food and Drug Administration (FDA) regulations: 21 CFR Parts 820, Quality System Regulations Non-harmonized Standards: EN ISO 15223-1:2012 ANSI Z400.1:2010 EU CLP - Regulation EC No 1272/2008

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: _____ Date: 25 March, 2016

Dave Wurtz, Director, Regulatory and Compliance

Diagnostics Division
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