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DECLARATION OF CONFORMITY

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

Date of Issue:	October 24, 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**
10015556	QMS® Tacrolimus Immunoassay	12.08.06.03	55445
10015573	QMS® Tacrolimus Immunoassay Calibrators	12.50.01.01	55443

Manufacturer:	Microgenics Corporation – Thermo Fisher Scientific 46500 Kato Road, Fremont, CA 94538, USA
Authorized Representative:	B·R·A·H·M·S GmbH, Neuendorfstraβe 25, 16761 Hennigsdorf, Germany
Notified Body:	TÜV Rheinland LGA Products GmbH, Tillystraβe 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 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: ANSI Z400.1:2010

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: 10·28·2016

Jeffrey J. Fisher, Director, Regulatory and Compliance

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