

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
100276	CEDIA [®] Mycophenolic Acid Assay	12.08.06.05	55450
10016265	CEDIA [®] Mycophenolic Acid Assay [Indiko]	12.08.06.05	55450
100277	CEDIA [®] Mycophenolic Acid Calibrators	12.50.01.01	55451
100278	MAS [®] Mycophenolic Acid Controls – Level 1	12.50.01.02	55452
100279	MAS [®] Mycophenolic Acid Controls – Level 2	12.50.01.02	55452
100280	MAS [®] Mycophenolic Acid Controls – Level 3	12.50.01.02	55452

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:	<ul style="list-style-type: none"> ▪ EN ISO 13485:2012 ▪ EN ISO 14971:2012 ▪ EN 13612:20002 ▪ EN 62366:2008 ▪ EN 980:2008 ▪ EN ISO 18113-1:2011 ▪ EN ISO 18113-2:2011 ▪ EN 13641:2002 ▪ EN ISO 23640:2015
Other regulations/ standards by which product is regulated:	<p>USA Food and Drug Administration (FDA) regulations: 21 CFR Parts 820, Quality System Regulations</p> <p>Non-harmonized Standards: ANZI Z400-1:2010, Material Data Safety Sheet Preparation EU CLP - Regulation EC No 1272/2008</p>

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: 
Jeffrey J. Fisher, Director, Regulatory and Compliance

Date: 09.28.2016