DECLARATION OF CONFORMITY

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

Date of Issue:	31-August-2009
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**: UAT-MP **Product Name**: MAS® UA Dip Tube
Manufacturer:	Microgenics Corporation, 46360 Fremont Blvd., Fremont, CA 94538, USA
Authorized Representative:	Microgenics GmbH, Spitalhotstrasse 94, 94036 Passau, Germany
Notified Body:	TUV Product Service GmbH, Ridlerstr 65, 80339 Munchen, Germany
Harmonized Standards Referenced:	▪ BS EN 375 ▪ BS EN 980 ▪ ISO 14971 ▪ BS EN 13612 ▪ BS EN 13640 ▪ BS EN 13641 ▪ ISO 13485:2003 ▪ ANSI Z400
Other standards by which product is regulated:	USA Food and Drug Administration (FDA) regulations: 1. 21 CFR Parts 820, Quality System Regulations 2. 21 CFR Parts 809, Labeling for IVD Products for Human Use 3. 21 CFR Parts 806, Medical Devices; Reports of Corrections and Removals

Microgenics Corporation's Quality Management System is certified to ISO 13485:2003 by TUV Product service GmbH. Certificate # Q1N 07 11 43837 005

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.

Signed: Hewuan Takkele Dated: 08/31/09

Hewuan Takkele, Regulatory Affairs Specialist