

EC DECLARATION OF CONFORMITY

Annex III Medical Devices for In Vitro Diagnostic (for professional use)  
Classification: General IVD Device

We

Microbiologics, Inc.  
200 Cooper Avenue North  
St. Cloud, MN 56303, USA

having designated:  
Medimark Europe Sarl, 11 rue Emile Zola – BP 2332  
38033 Grenoble Cedex 2 France  
As our European Authorized Representative

having our Quality Management System been certified against ISO13485:2016 standard  
(Certificate N° FM 595607 BSI Group America, Inc),

insure and declare under our sole responsibility that the Medical Devices for In Vitro Diagnostic  
specified in the attached list to which this declaration relates are in conformity with the  
requirements of the Directive 98/79/EC on In Vitro Medical Devices.

This declaration is made in accordance with Annex III of the Directive 98/79/EC on In Vitro  
Medical Devices and is valid for an undetermined period of time.

St. Cloud, MN USA, 09/13/2017



*Scott A. Palasewski*  
9-13-17

Name of the authorized person: Donna Scholer  
Title: Chief Operating Officer

Signature: *Donna Scholer*

**List of Annex 3 Medical Devices for In Vitro diagnostic for professional use  
 in relation with the above declaration**

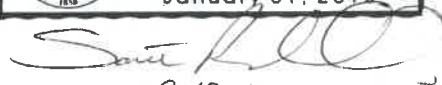
Catalog #	Product Name
FP01	Giardia lamblia
FP02	Cryptosporidium species
FP03	Diphyllobothrium latum
FP04	Taenia species
FP05	Ascaris lumbricoides
FP06	Strongyloides stercoralis
FP07	Blastocystis hominis
FP08	Trichuris trichiura
FP09	Iodamoeba butschlii
FP10	Necator americanus
FP11	Hymenolepis nana
FP12	Endolimax nana
FP13	Entamoeba coli Parasite Suspension

St. Cloud, MN USA, 09/13/2017

Name of the authorized person: Donna Scholer  
 Title: Chief Operating Officer

Signature: 



  
 9-13-17



DECLARATION N°: TF04 SEPTEMBER 2017