



Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Certificate No. 122-1-2011

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

Name of Manufacturer/Distributor Address

See attached list  
(One Page)

Catheter Research, Inc DbA Thomas Medical, Inc.  
5610 West 82<sup>nd</sup> Street  
Indianapolis, IN 46278

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the products(s) listed above.

Chester T. Reynolds  
Acting Deputy Director,  
Division of Risk Management Operations  
Office of Compliance  
Center for Devices and Radiological Health

**This certificate expires 24 months  
from the date notarized.**

COUNTY OF MONTGOMERY  
STATE OF MARYLAND

Subscribed and sworn to before me this 27 day of Sept month 2011 year.

CATHRYN N. MORRIS  
NOTARY PUBLIC STATE OF MARYLAND  
County of Montgomery  
My Commission Expires January 4, 2013



**Certificate to Foreign Government – Attachment (page 1 of 1)**

<b>Name of Products</b>	<b>Name of Manufacturer/Distributor Address</b>
TMI1151: Uterine Manipulator/Injector	Catheter Research, Inc. Dba Thomas Medical, Inc. 5610 West 82 <sup>nd</sup> Street Indianapolis, IN 46278
TMI1152: Uterine Injector	
TMI1153: Uterine Injector	
TMI1154: HS and SHG catheter	
TMI1155: HS and SHG catheter	
TMI1185: Shapeable HS and SHG catheter	
TMI1187: Shapeable HS and SHG catheter	
TMI1162: SHG Catheter	
TMI1170: SHG Catheter	
TMI1171: Uterine Manipulator/Injector	
TMI1175: Endometrial sampler	
OS-01-001: Flexible Cervical Dilator	
US-01-001: Uterine Sound	
LE-xx-xxx: Thomas Medical Electrodes	
Surgical Instruments	
<b>*END OF PRODUCT LIST*</b>	

