



Certificate No. 3209-4-2008

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

<u>Name of Product(s)</u>	<u>Name of Manufacturer/Distributor Address</u>
Disposable Surgical Drapes And Accessories	Medical Concepts Development 2500 Ventura Drive Woodbury, MN 55125
Trade Name: Acti-gard Antimicrobial Surgical Drapes	
See attached list (2 pages)	

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 product(s) listed above.

Theresa McDonald
Chief, Regulatory Policy and Systems Branch
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 13 day of May month 2008 year.

CATHRYN N. ADAMS
NOTARY PUBLIC STATE OF MARYLAND
County of Montgomery
My Commission Expires January 1, 2009



Certificate to Foreign Government - Attachment (page 1 of 2)

<u>Part Number</u>	<u>Product Description</u>	<u>Manufacturer:</u>
D1000 /NP/RL	Small Towel Drape	Medical Concepts Development
D1003	Isolation Bag	2500 Ventura Drive
D1010 /NP/ RL	Large Towel Drape	Woobury, MN 55125
D1012	Fluoroscope Cover	
D1013	C-Arm Cover	
D1014	Patient Isolation Drape	
D1015	Poly U-Drape	
D1016	Large Fluid Pouch	
D1017	Patient Isolation Drape with Pouch	
D1018	Instrument Pouch	
D1019/NS/PNS	Poly U-Drape	
D1020	Small Aperture Drape	
D1021	Small Ophthalmic Incise Drape	
D1022	Refractive Drape	
D1024	Large Aperture Pouch	
D1025	Large Incise Pouch	
D1030	Large Aperture Drape	
D1031	Large Aperture Drape with Pouch	
D1035	Min. Incise Drape	
D1040	Medium Incise Drape	
D1050	Large Incise Drape	
D1051	Extra Large Incise Drape	
D1060	Ophthalmic Incise Drape	
D1061	Ophthalmic Incise Drape with Pouch	
D1062	Ophthalmic Incise Drape with Pouch	
D1064	Aperture Ophthalmic Sheet	
D1065	Ophthalmic Incise Sheet	
D1067	U-Drape with Pouch	
D1071	Urological Drape	
D1072	Aperture Pouch	
D1089	Utility Drape	
D1092	Minor Procedure Drape	
D1093	Absorbent Femoral Angiography Sheet	
D1122	Refractive Drape	
D1164	Ophthalmic Aperture Sheet	
D1165	Ophthalmic Incise Sheet	
D1191	Absorbent Femoral Angiography Sheet	
D1195	Absorbent Femoral Angiography Sheet	
D1295	Absorbent Femoral Angiography Sheet	
D1395	Angiography Sheet	
D1495	Angiography Sheet	
D1595	Angiography Sheet	
D2007	Clear Poly Cover	
D2008	Clear Poly Cover	
D2019	Ophthalmic Incise Drape	
D2020	Ophthalmic Aperture Drape	
D2021	Small Irrigation Pouch	
D2024	"Slush" Drape	
D2029	Poly Tape Strip	
D2043	Strabismus Drape	
D2057	Cesarean Section Pouch	
G2076NS	Absorbent Floor Mat	
D2085	PeriOB Drape	



Certificate to Foreign Government - Attachment (page 2 of 2)

<u>Part Number</u>	<u>Product Description</u>	<u>Manufacturer:</u>
D2097	Cesarean Incise Sheet w/Pouch	Medical Concepts Development
D2114	Medium Irrigation Pouch	2500 Ventura Drive
D2147	Aperture Drape	Woobury, MN 55125
D2158	Instrument Cover	
D2168	Craniotomy Sheet	
D2221	Fluoroscope Procedure Sheet	
D2224	Special Procedure Sheet	
D2244	Absorbent Femoral Angiography Sheet	
D2246NS	Absorbent Floor Mat	
D2252	Absorbent Femoral Angiography Sheet	
D2258	Ophthalmic Incise Sheet	
D2260	Subclavian Drape	
D2264	Fistula Drape	
D2286	Absorbent Femoral Angiography Sheet	
D371049	Vi-Drape 7" Wound Protector	
D371053	Vi-Drape Surgical Film 24"x42"	
D371054	Vi-Drape Surgical Film 24"x18"	
D371055	Vi-Drape Isolation Bag	
D37106210	Vi-Drape® Wound Protector, 12 cm Ring	
D37106310	Vi-Drape® Wound Protector, 23 cm Ring	
D37106410	Vi-Drape® Wound Protector, 28 cm Ring	
D37612210	Vi-Drape® Wound Protector, 7 cm Ring	
D376205	Vi-Drape Adhesive Spray	
D37624310	Vi-Drape® Incise Drape 24 cm x 25 cm	
D37624410	Vi-Drape® Incise Drape 32 cm x 45 cm	
D37624510	Vi-Drape® Incise Drape 48 cm x 45 cm	
D37624610	Vi-Drape® Incise Drape 96 cm x 60 cm	
D37624710	Vi-Drape® Incise Drape 30 cm x 85 cm	
D6617	ACTI-Gard® Antimicrobial Patient Isolation Drape	
D6619	ACTI-Gard® Antimicrobial Patient Isolation Drape	
D6621	ACTI-Gard® Antimicrobial Fluoroscope Special Procedure Sheet	
D6622	ACTI-Gard® Antimicrobial Pacer Sheet	
D6635	ACTI-Gard® Antimicrobial Incise Drape, 6 in. x 7.75 in.	
D6640	ACTI-Gard® Antimicrobial Incise Drape, 20 in. x 14 in.	
D6648	ACTI-Gard® Antimicrobial Incise Drape, 30 in. x 23.5 in.	
D6650	ACTI-Gard® Antimicrobial Incise Drape, 30 in. x 18 in.	
D6651	ACTI-Gard® Antimicrobial Incise Drape, 30 in. x 35.5 in.	
D6657	ACTI-Gard® Antimicrobial Cesarean Pouch	
D6697	ACTI-Gard® Antimicrobial Cesarean Incise Sheet	

END OF PRODUCT LIST

