U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FDA Industry Systems

SYSTEM STATUS | HELP DESK

LOGIN

Existing account holders, enter your account ID & password.
Account ID:

gns21746

Password:

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I Understand

login | Forgot your password?

NEW USER

- Create New Account
- See Instructions
- See Tutorials
- Help Desk

GETTING STARTED

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" below.

If you already have an account, enter your **account ID** and **password**.

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and Anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact **FDA FURLS Helpdesk at 1-800-216-7331** to confirm that the caller is acting on behalf of FDA.

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Account Management

- **Account Management**
- Edit Account Profile
- Change My Password
- Update System Access
- Create a Subaccount
- Deactivate a Subaccount
- Reactivate a Subaccount

WELCOME You are logged in as **gns21746**

Welcome to the FDA Industry Systems.

You are logged in to your account for company **gnsi**

You may choose an option on the left to manage your account or select an FDA system below.
To obtain access to available FDA systems, choose the Update System Access option to add the FDA system to your account.

FDA UNIFIED REGISTRATION LISTING SYSTEMS

- Food Facility Registration
- Device Registration & Listing
- Shell Egg Registration
- Drug Facility Registration
- Acidified/Low Acid Canned Foods
- Certificate Application Process
- CDRH Export Certificate Application & Tracking System

OTHER FDA SYSTEMS

- Prior Notice of Imported Food

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CECATS MAIN MENU

Enter New Application

Modify Application

Search Application

Form Approval: OMB No.0910-0498

Expiration date:3/31/2015
See OMB Statement at end of form

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please Note:

The system will automatically time out if there is no activity for 30 minutes and you will need to re-do your work from the beginning.

CECATS CDRH Export Certificate Application and Tracking System

Get Help

Please select the certificate type you are applying for. If you are unsure as to which one to select, please click on the "ICON" for a description of each certificate type.

*** - These fields are required**

Certificate Type :

Certificate to Foreign Government (CFG)

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SECTION 1 REQUESTOR INFORMATION

If the information below is incorrect, you will need to update your account before proceeding any further . Click on here to navigate to the Online Account Administration to make the necessary updates.

*** - These fields are required**

*Salutation
Mr.

*First Name
Vijay

Middle Initial

*Last Name
Maringanti

*Title
sw

*Firm
gnsi

*Country / Area
UNITED STATES

*Address Line 1
11820 Parklawn DR

Address Line 2
300

*Zip Code (Postal Code)

20852

* City

Rockville

*State / Province / Territory

Maryland

Numbers only. No spaces, dashes or parentheses. Country Code is not required for U.S. phone numbers.

	Country Code (e.g.001)	Area / City Code (e.g.101)	*Phone Number (e.g.5551111)	Extension (e.g.1111)
*Phone Number		301	4656565	

	Country Code (e.g.001)	Area / City Code (e.g.101)	Fax Number (e.g.5551111)
Fax Number			

*Firm Tax ID Code

12 - 1211111

*Email Address

vijayasarathi.maringanti@fda.hhs.gov

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STEP1 ADDRESS VALIDATION

This address has been verified; however minor modifications were made to the information you entered. Please indicate whether you wish to accept the modifications we made, or Click on FURLSHome to navigate to the Online Account Administration to make the necessary updates.

YOUR ADDRESS	VALIDATED ADDRESS
REQUESTOR FIRM NAME: gnsi	REQUESTOR FIRM NAME: gnsi
REQUESTOR FIRST NAME: Vijay	REQUESTOR FIRST NAME: Vijay
REQUESTOR LAST NAME: Maringanti	REQUESTOR LAST NAME: Maringanti
STREET ADDRESS, Line 1: 11820 Parklawn DR	**STREET ADDRESS, Line 1:** 11820 Parklawn Dr Ste 300
STREET ADDRESS, Line 2: 300	**STREET ADDRESS, Line 2:**
CITY: Rockville	**CITY:** Rockville
STATE: Maryland	**STATE:** Maryland
ZIP/POSTAL CODE: 20852	**ZIP/POSTAL CODE:** 20852-2529
COUNTRY: UNITED STATES	**COUNTRY:** UNITED STATES

⊙Accept validated address and continue

Continue

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SECTION 2 MANUFACTURER INFORMATION

The FDA requires that all facilities manufacturing medical devices must be registered in the FDA Device Registration and Listing Facility(DRLM) system. Once a manufacturer is registered in the DRLM, the FDA provides an Owner Operator Number to the requesting firm. The FDA also assigns a Registration number for every manufacturer registered in DRLM.If you have not registered your manufacturer in DRLM, click on here to navigate to DRLM and register your manufacturer. Otherwise, please enter the Registration Number or the Owner Operator Number.

* - These fields are required

*Registration Number :

OR

*Owner Operator Number : 10033918

Retrieve Registrations

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SECTION 2 MANUFACTURER INFORMATION

Please select a manufacturer(s) and click add.

NOTE: Only a manufacturer in an "Active" or "Active Pending Registration Number" status in DRLM can be selected.

	Firm	Registration Number	Status	Address (P.O. Box not acceptable)
☑	GNSI - Class I Exempt Only With Inspection		Active	311 W Side Dr Apt 301 , Gaithersburg , Maryland UNITED STATES , 20878
☐	GNSI - Class I Exempt Only With No Inspection		Active	11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852

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SECTION 2 MANUFACTURER INFORMATION

The following manufacturer(s) has been added to the certificate request.

Firm	Registration Number	Status	Address (P.O. Box not acceptable)
GNSI - Class I Exempt Only With Inspection		Active	311 W Side Dr Apt 301 , Gaithersburg, Maryland UNITED STATES , 20878

Do you want to add another manufacturer? (•) Yes ( ) No

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SECTION 2 MANUFACTURER INFORMATION

The FDA requires that all facilities manufacturing medical devices must be registered in the FDA Device Registration and Listing Facility(DRLM) system. Once a manufacturer is registered in the DRLM, the FDA provides an Owner Operator Number to the requesting firm. The FDA also assigns a Registration number for every manufacturer registered in DRLM.If you have not registered your manufacturer in DRLM, click on here to navigate to DRLM and register your manufacturer. Otherwise, please enter the Registration Number or the Owner Operator Number.

* - These fields are required

*Registration Number : 786898

OR

*Owner Operator Number :

Retrieve Registrations

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SECTION 2 MANUFACTURER INFORMATION

Please select a manufacturer(s) and click add.

NOTE: Only a manufacturer in an "Active" or "Active Pending Registration Number" status in DRLM can be selected.

	Firm	Registration Number	Status	Address (P.O. Box not acceptable)
☑	RICK'S MEDICAL DEVICE FIRM(510k)	786898	Active	11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852

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SECTION 2 MANUFACTURER INFORMATION

The following manufacturer(s) has been added to the certificate request.

Firm	Registration Number	Status	Address (P.O. Box not acceptable)
RICK'S MEDICAL DEVICE FIRM(510k)	786898	Active	11820 Parklawn Dr Ste 300 , Rockville, Maryland UNITED STATES , 20852

Do you want to add another manufacturer? ○ Yes ◉ No

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SECTION 2 MANUFACTURER INFORMATION

*** - These fields are required**

Firm Name
GNSI - Class I Exempt Only With Inspection

Registration Number

Address Line 1
311 W Side Dr Apt 301

Address Line 2

City
Gaithersburg

State / Province / Territory
Maryland

*Country / Area
UNITED STATES

Zip Code (Postal code)
20878

License Number (if applicable)


Date of Last FDA inspection (MM/DD/YYYY)
03/01/2011
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SECTION 2 MANUFACTURER INFORMATION

The following manufacturer(s) has been added to the certificate request.
You may optionally enter the Date of Last FDA Inspection by selecting the manufacturer and clicking on "Edit".

You can add an additional manufacturer by clicking on "Add".
You can remove an existing manufacturer by selecting a manufacturer and clicking on "Remove".

	Firm	Registration Number	License number(if applicable)	Date of Last FDA Inspection	Address (P.O. Box not acceptable)
○	GNSI - Class I Exempt Only With Inspection			03/01/2011	311 W Side Dr Apt 301, Gaithersburg, Maryland UNITED STATES , 20878
○	RICK'S MEDICAL DEVICE FIRM(510k)	786898			11820 Parklawn Dr Ste 300, Rockville, Maryland UNITED STATES , 20852

Edit | Remove | Add

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SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

The FDA requires that all facilities manufacturing medical devices must be registered in the FDA Device Registration and Listing Facility(DRLM) system. Once a distributor is registered in the DRLM, the FDA provides an Owner Operator Number to the requesting firm. The FDA also assigns a Registration number for every distributor registered in DRLM.If you have not registered your distributor in DRLM, click on here to navigate to DRLM and register your distributor. Otherwise, please enter the Registration Number or the Owner Operator Number.

* - These fields are required

*Registration Number : 786898

OR

*Owner Operator Number :

Retrieve Registrations

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SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

Please select a distributor(s) and click add.

NOTE: Only a domestic distributor in an "Active" or "Active Pending Registration Number" status in DRLM can be selected.

	Firm	Registration Number	Status	Address (P.O. Box not acceptable)
☑	RICK'S MEDICAL DEVICE FIRM(510k)	786898	Active	11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852

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SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

The following distributor(s) has been added to the certificate request.

Firm	Registration Number	Status	Address (P.O. Box not acceptable)
RICK'S MEDICAL DEVICE FIRM(510k)	786898	Active	11820 Parklawn Dr Ste 300 , , Rockville, Maryland, UNITED STATES , 20852

Do you want to add more distributor's? ○ Yes ◉ No

Continue

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SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

The following distributor(s) has been added to the certificate request.

Select	Firm	Registration Number	Address (P.O. Box not acceptable)
⊙	RICK'S MEDICAL DEVICE FIRM(510k)	786898	11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852

Remove | Add

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SECTION 4 PRODUCT INFORMATION

Warning: You may list Class III products only if the manufacturing facility has been inspected by the FDA. Failure to comply will prompt the FDA to immediately reject the certificate request.

*Will you be listing any refurbished or remanufactured products in this application? ⊙ Yes ○ No

*Are you the original manufacturer of this product(s)? ○ Yes ⊙ No

Please be advised that any refurbished or remanufactured product cannot appear on the certificate unless you are the original manufacturer.

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SECTION 4 PRODUCT INFORMATION

In this section you will be able to retrieve all products associated to a facility registered in DRLM.
Please select a facility and click on "Add/Remove Product"
NOTE: You must select at least one product for each facility listed below in order to continue.

Select	Manufacturer	Product Details
⊙	GNSI - Class I Exempt Only With Inspection	
○	RICK'S MEDICAL DEVICE FIRM(510k) 786898	

Select	Distributor	Product Details
○	RICK'S MEDICAL DEVICE FIRM(510k) 786898	

Add/Remove Product

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SECTION 4 PRODUCT INFORMATION

Please select the product(s) for this facility.You may optionally enter the Trade Name and or Proper Name for each product selected.

If you wish to have the Proper Name printed on the certificate, you will need to enter the Proper Name for each product.
NOTE: Only the Proper Name can be printed on the certificate.

	Marketing Status	Product Code	Product Name	Trade Name	Proper Name
☑	Exempt	JCF	LYMPHOCYTE SEPARATION MEDIUM	tn1	pn1
☐	Exempt	GIF	DILUENT, BLOOD CELL		

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SECTION 4 PRODUCT INFORMATION

Please select the product(s) for this facility.You may optionally enter the Trade Name and or Proper Name for each product selected.

If you wish to have the Proper Name printed on the certificate, you will need to enter the Proper Name for each product.
NOTE: Only the Proper Name can be printed on the certificate.

	Marketing Status	Product Code	Product Name	Trade Name	Proper Name
☑	Exempt	JCF	LYMPHOCYTE SEPARATION MEDIUM	tn1	pn1
☐	Exempt	GIF	DILUENT, BLOOD CELL		

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SECTION 4 PRODUCT INFORMATION

In this section you will be able to retrieve all products associated to a facility registered in DRLM.
Please select a facility and click on "Add/Remove Product"
NOTE: You must select at least one product for each facility listed below in order to continue.

Select	Manufacturer	Product Details		
		Trade Name	**Proper Name**	**Marketing Status**
○	GNSI - Class I Exempt Only With Inspection	tn1	pn1	Exempt
⊙	RICK'S MEDICAL DEVICE FIRM(510k) 786898			

Select	Distributor	Product Details
○	RICK'S MEDICAL DEVICE FIRM(510k) 786898	

Add/Remove Product

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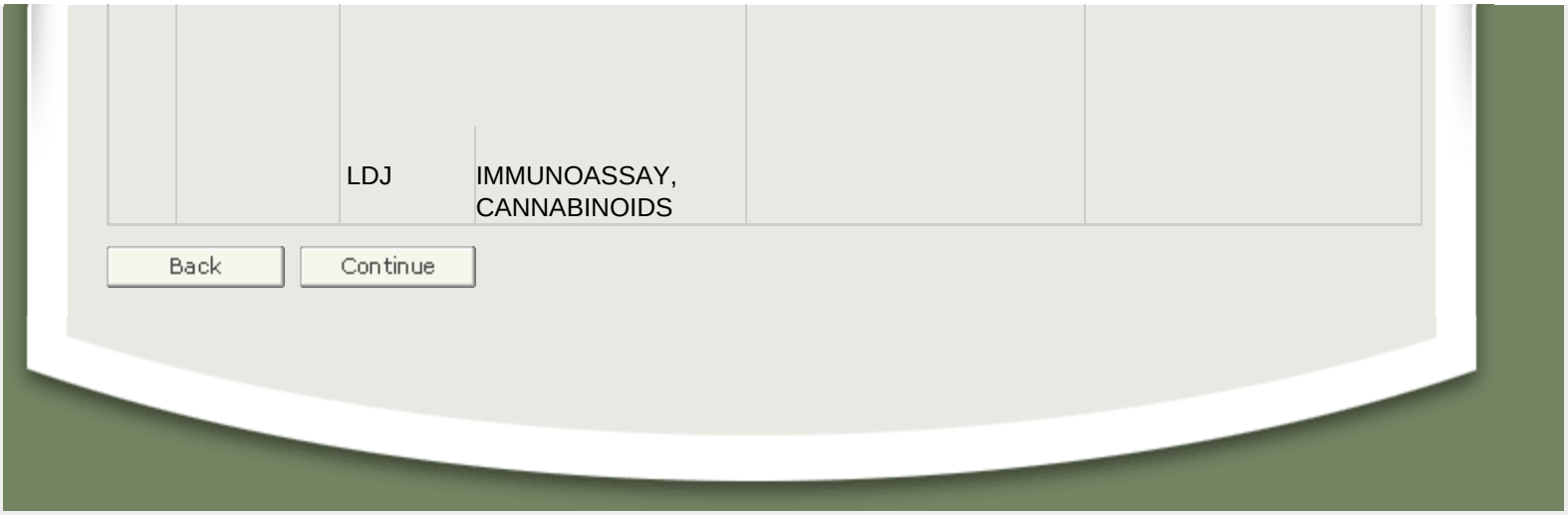
SECTION 4 PRODUCT INFORMATION

Please select the product(s) for this facility.You may optionally enter the Trade Name and or Proper Name for each product selected.

If you wish to have the Proper Name printed on the certificate, you will need to enter the Proper Name for each product.
NOTE: Only the Proper Name can be printed on the certificate.

	Marketing Status	Product Code	Product Name	Trade Name	Proper Name
☑	K991735	DPS	ELECTROCARDIOGRAPH	Trade Name2	Proper Name2
		DQK	COMPUTER, DIAGNOSTIC, PROGRAMMABLE		
		DXH	TRANSMITTERS AND RECEIVERS, ELECTROCARDIOGRAPH, TELEPHONE		
		LOS	System, ecg analysis		
☑	K974749	KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	Trade Name3	Proper Name3
		KWQ	APPLIANCE, FIXATION, SPINAL INTERVERTEBRAL BODY		
		MNH	Orthosis, spondylolisthesis spinal fixation		
☐	K992748	DIO	ENZYME IMMUNOASSAY, COCAINE AND COCAINE METABOLITES		
		DKZ	ENZYME IMMUNOASSAY, AMPHETAMINE		
		DPK	LIQUID CHROMATOGRAPHY, MORPHINE		
		LCM	Enzyme immunoassay, phencyclidine		
			ENZYME		


LDJ
IMMUNOASSAY, CANNABINOIDS
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SECTION 4 PRODUCT INFORMATION

In this section you will be able to retrieve all products associated to a facility registered in DRLM.
Please select a facility and click on "Add/Remove Product"
NOTE: You must select at least one product for each facility listed below in order to continue.

Select	Manufacturer	Product Details		
○	GNSI - Class I Exempt Only With Inspection	**Trade Name**	**Proper Name**	**Marketing Status**
		tn1	pn1	Exempt
○	RICK'S MEDICAL DEVICE FIRM(510k) 786898	**Trade Name**	**Proper Name**	**Marketing Status**
		Trade Name2	Proper Name2	K991735
		Trade Name3	Proper Name3	K974749

Select	Distributor	Product Details
⊙	RICK'S MEDICAL DEVICE FIRM(510k) 786898	

Add/Remove Product

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SECTION 5 WAS THE PRODUCT EVER RECALLED?

If any product listed below has ever been recalled, please place a checkmark next to the product and enter the FDA Issued Recall Number.

Once completed, click on "Continue"

Recalled	Firm	Marketing Status	Product Code	Product Name
☑	GNSI - Class I Exempt Only With Inspection	Exempt	JCF	LYMPHOCYTE SEPARATION MEDIUM
	FDA Issued Recall Number : Z- 1039 - 05			**Close-out Date (MM/DD/YYYY) :**
☐	RICK'S MEDICAL DEVICE FIRM(510k)	K991735	DPS	ELECTROCARDIOGRAPH
			DQK	COMPUTER, DIAGNOSTIC, PROGRAMMABLE
			DXH	TRANSMITTERS AND RECEIVERS, ELECTROCARDIOGRAPH, TELEPHONE
			LOS	System, ecg analysis
	FDA Issued Recall Number : Z- -			**Close-out Date (MM/DD/YYYY) :**
☐	RICK'S MEDICAL DEVICE FIRM(510k)	K974749	KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL
			KWQ	APPLIANCE, FIXATION, SPINAL INTERVERTEBRAL BODY
			MNH	Orthosis, spondylolisthesis spinal fixation
	FDA Issued Recall Number : Z- -			**Close-out Date (MM/DD/YYYY) :**

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SECTION 5 WAS THE PRODUCT EVER RECALLED?

Our records indicate that the product(s) listed below does not have a recall close-out date. If available, please upload the official Close-Out Letter for each recalled product. Failure to do so may cause a delay in the certificate processing.

NOTE: The Close-Out Letter attachment cannot exceed 50MB (Megabytes).
The total file size of all Close-Out Letter attachments cannot exceed 50MB (Megabytes).
The accepted file formats include pdf, bmp, jpeg, gif, png, tiff, doc, and docx.

Firm	Product Code	Product Name	FDA Issued Recall Number	Close-out-Letter
GNSI - Class I Exempt Only With Inspection	JCF	LYMPHOCYTE SEPARATION MEDIUM	Z-1039-05	Upload

Back | Save & Exit | Continue to Step 6 | Cancel & Start Again

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SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED

*NAME OF COUNTRY or COUNTRIES

AFGHANISTAN
ALAND ISLANDS
ALBANIA
ALGERIA
AMERICAN SAMOA
ANDORRA
ANGOLA
ANGUILLA

ANDORRA

» Add
» Remove

AFGHANISTAN
ALAND ISLANDS

Back to Step 5 | Save & Exit | Continue to Step 7 | Cancel & Start Again

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Cancel & Start Again

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

***Please select primary facility :** GNSI - Class I Exempt Only With Inspection - Manufacturer

*Do you want to display the owner operator address for the primary facility selected on the certificate ? ○ Yes ◉ No

Back to Step 6 | Save & Exit | Continue
Cancel & Start Again

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SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Select the facilities and Header / Sub header names that you wish to appear on the certificate :

Select	Manufacturer	Header Name	SubHeader Name
☑	GNSI - Class I Exempt Only With Inspection	Name of Manufacturer/Distributor	Manufacturing Facility
☑	RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As

Formerly Known As : Former Firm Name goes here

Select	Distributor	Header Name	SubHeader Name
☑	RICK'S MEDICAL DEVICE FIRM(510k)	Name of Distributor	Manufactured For

Manufactured For : Manufacturer firm name goes here.

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Cancel & Start Again

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SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

NOTE: If you have not entered all of the Proper Names for each product in section 4, please go back and enter the information, or you will not be able to select "Use the existing product listing (from section 4) to appear on the certificate?"

- (•) Use the existing product listing (from section 4) to appear on the certificate?

OR

- ( ) Upload your product accessories?

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Restart Step 7

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

This section allows you to associate each product or product listing to one or more facilities that have been identified to be printed on the certificate. The associations you create will impact the printout of your certificate.

Select one or multiple products from each page. Then select one or more facilities. When you are finished, click on "Group". Continue grouping the remaining products until all products from the first page has been grouped. Click on the "Next" hyperlink to continue to the next set of products (if available).

NOTE: You must associate each product to at least one facility. If there are multiple pages of products, you must associate the products for each page before continuing to the next page of products.

Refer to the online help for more detailed instructions on product groupings and an example of a certificate printout.

☐	Products	Owner Operator / Manufacturer(s) / Distributor(s)
☐	pn1	**Manufacturer(s)**
☐	Proper Name2	☐ GNSI - Class I Exempt Only With Inspection
☐	Proper Name3	☐ RICK'S MEDICAL DEVICE FIRM(510k)-786898
		Distributor(s)
		☐ RICK'S MEDICAL DEVICE FIRM(510k)-786898

Clear Group | Group

Clear All Groupings | Group All Products to All Facilities

Restart Step 7 | Review Product Groupings

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SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

NOTE: If you have not entered all of the Proper Names for each product in section 4, please go back and enter the information, or you will not be able to select "Use the existing product listing (from section 4) to appear on the certificate?"

○ Use the existing product listing (from section 4) to appear on the certificate?
OR
⊙ Upload your product accessories?

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SECTION 7 **INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE**

The maximum allowed file size is 50 MB (Megabytes).The accepted file types are Microsoft 2007 or 2010 Excel Spreadsheets (.xls or .xlsx). Click **here** to download the product template file.

Select the file to upload:

Upload

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SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

This section allows you to associate each product or product listing to one or more facilities that have been identified to be printed on the certificate. The associations you create will impact the printout of your certificate.

Select one or multiple products from each page. Then select one or more facilities. When you are finished, click on "Group". Continue grouping the remaining products until all products from the first page has been grouped. Click on the "Next" hyperlink to continue to the next set of products (if available).

NOTE: You must associate each product to at least one facility. If there are multiple pages of products, you must associate the products for each page before continuing to the next page of products.

Refer to the online help for more detailed instructions on product groupings and an example of a certificate printout.

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Products	Owner Operator / Manufacturer(s) / Distributor(s)
Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo noteched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L Raspatories , FREER , 18.5 cm C.S. Mirror #4 C.S. Mirror #4 12 pack C.S. Mirror #5 C.S. Mirror #5 12 Pack Gracey Deep Pocket 1-2 xp 3/8" Resin Gracey Deep Pocket 1-2 xp 3/8" Stainless Gracey Deep Pocket 3-4 xp 3/8" Resin Gracey Deep Pocket 3-4 xp 3/8" Stainless Cassette SL5 (5 Instr) Cassette SL5 (7 Instr - no rack) Cassette 108(8 Instr)	RICK'S MEDICAL DEVICE FIRM(510k)-786898(Manufacturer)

Cassette 108 utility (8 Instr) Cassette 108 Removable Rack(8-16 Instr) Cassette 109 W/12 Slots	

☐	Products	Owner Operator / Manufacturer(s) / Distributor(s)
☑	Extracting forceps , American Pattern , Fig A 151 S	**Manufacturer(s)**
☑	Pillers , Endo noteched Locking	☐ RICK'S MEDICAL DEVICE FIRM(510k)-786898
☑	Needle holders, CRILE-WOOD , 15cm	**Distributor(s)**
☑	Needle holders, DERF , 12.5cm	☐ RICK'S MEDICAL DEVICE FIRM(510k)-786898
☑	Needle holders, MAYO-HEGAR , 16cm	
☑	Rubberdam punch , IVORY	
☑	Rubberdam punch , AINSWORTH	
☑	Rubberdam clamp forceps ; BREWER	
☑	Hemostatic forceps , KELLY , 14cm	
☑	Hemostatic forceps , KELLY , 14cm , Curved	
☑	Cheek retractors , CAEWOOD-MINNESOTA , 16cm	
☑	Crown Scissors , BEEBEE , 10.5 cm	
☑	Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape.	
☑	Root Elevators , FLOHR L	
☑	Root Elevators , CRYER L	
☑	Raspatories , FREER , 18.5 cm	
☑	C.S. Mirror #4	
☑	C.S. Mirror #4 12 pack	
☑	C.S. Mirror #5	
☑	C.S. Mirror #5 12 Pack	
☑	Gracey Deep Pocket 1-2 xp 3/8" Resin	
☑	Gracey Deep Pocket 1-2 xp 3/8" Stainless	
☑	Gracey Deep Pocket 3-4 xp 3/8" Resin	
☑	Gracey Deep Pocket 3-4 xp 3/8" Stainless	
☑	Cassette SL5 (5 Instr)	
☑	Cassette SL5 (7 Instr - no rack)	
☑	Cassette 108(8 Instr)	
☑	Cassette 108 utility (8 Instr)	
☑	Cassette 108 Removable Rack(8-16 Instr)	
☑	Cassette 109 W/12 Slots	

>> Next

Clear Group | Group

Clear All Groupings | Group All Products to All Facilities | Reupload Products

Restart Step 7 | Review Product Groupings

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SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

This section allows you to associate each product or product listing to one or more facilities that have been identified to be printed on the certificate. The associations you create will impact the printout of your certificate.

Select one or multiple products from each page. Then select one or more facilities. When you are finished, click on "Group". Continue grouping the remaining products until all products from the first page has been grouped. Click on the "Next" hyperlink to continue to the next set of products (if available).

NOTE: You must associate each product to at least one facility. If there are multiple pages of products, you must associate the products for each page before continuing to the next page of products.

Refer to the online help for more detailed instructions on product groupings and an example of a certificate printout.

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☑	Products
☑	Probe 1 Yellow 7/32" stainless
☑	Probe 1 Yellow 3/8 " Resin
☑	Probe 12 Yellow 7/32 " Resin
☑	Probe 12 Yellow 7/32 " Stainless
☑	Explorer 23 (SE) 3/8" Resin
☑	Explorer 2 (DE) 3/8" Resin
☑	Explorer 3 (SE) 7/32" Stainless
☑	Curette Columbia 12-14 xp 3/8" Resin
☑	Curette Columbia 12-14 xp 3/8" Stainless
☑	Curette Columbia 12-14 xp 7/32" Resin
☑	Waxing PKT 1 1/4" Stainless

Owner Operator / Manufacturer(s) / Distributor(s)
Manufacturer(s)
☑ RICK'S MEDICAL DEVICE FIRM(510k)-786898
Distributor(s)
☑ RICK'S MEDICAL DEVICE FIRM(510k)-786898

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Clear Group | Group

Clear All Groupings | Group All Products to All Facilities | Reupload Products

Restart Step 7 | Review Product Groupings

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SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Products	Owner Operator/Manufacturer(s)/Distributor(s)
Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo noteched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L Raspatories , FREER , 18.5 cm C.S. Mirror #4 C.S. Mirror #4 12 pack C.S. Mirror #5 C.S. Mirror #5 12 Pack Gracey Deep Pocket 1-2 xp 3/8" Resin Gracey Deep Pocket 1-2 xp 3/8" Stainless Gracey Deep Pocket 3-4 xp 3/8" Resin Gracey Deep Pocket 3-4 xp 3/8" Stainless Cassette SL5 (5 Instr) Cassette SL5 (7 Instr - no rack) Cassette 108(8 Instr) Cassette 108 utility (8 Instr) Cassette 108 Removable Rack(8-16 Instr) Cassette 109 W/12 Slots	RICK'S MEDICAL DEVICE FIRM(510k)-786898(Manufacturer)
Probe 1 Yellow 7/32" stainless Probe 1 Yellow 3/8 " Resin Probe 12 Yellow 7/32 " Resin Probe 12 Yellow 7/32 " Stainless Explorer 23 (SE) 3/8" Resin Explorer 2 (DE) 3/8" Resin Explorer 3 (SE) 7/32" Stainless Curette Columbia 12-14 xp 3/8" Resin Curette Columbia 12-14 xp 3/8" Stainless Curette Columbia 12-14 xp 7/32" Resin	RICK'S MEDICAL DEVICE FIRM(510k)-786898(Manufacturer) RICK'S MEDICAL DEVICE FIRM(510k)-786898(Distributor)


Waxing PKT 1 1/4" Stainless
Back to Step 6
Save & Exit
Continue to Step 8
Cancel & Start Again

CECATS CDRH Export Certificate Application and Tracking System

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Back to Step 7 | Save & Exit | Continue to Step 9 | Cancel & Start Again

SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE?

(Note : CDRH does not list a specific country on a certificate.)

Should the country destination be listed on the certificate ? ○ Yes ◉ No

Indicate the total number of certificates requested : 12

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SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

Department of Health and Human Services Food and Drug Administration	**EXPORTER'S CERTIFICATION STATEMENT "CERTIFICATE TO FOREIGN GOVERNMENT " for CDRH**

Primary Facility : RICK'S MEDICAL DEVICE FIRM(510k) - Manufacturer

As a responsible official or designee authorized to represent and act on behalf of the facility named immediately above, I hereby certify to the Food and Drug Administration (FDA) that the facility(s) and the products identified on the Supplemental Information are to the best of my knowledge in substantial compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations including the following:

1. All Facilities that appear on the certificate are currently registered and each facility has listed each of its medical devices identified for export as required by Section 510 of the Act and 21 CFR Part 807 (See attached Supplementary Information Page);
2. Each product(s) identified for export is legally marketed within the United States and is the subject of a 510(k) premarket notification or is a device that was in commercial distribution before May 28, 1976, or exempt, or is the subject of a premarket approval application;
3. Each product(s) identified is not subject of an open recall or the subject of any current enforcement action initiated by FDA ; and
4. All manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process have been identified on the 3613 form.
5. The requesting facility and all facilities involved in the manufacturing process are operating in substantial compliance with the Good Manufacturing Practices Regulation (21 CFR Part 820) for the identified product(s).
6. There are no HIV products listed on the certificate.
7. Each product(s) identified for export is being exported from the United States.

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submission of false statements represents violations of United State Code Title 18, Chapter 47, Section 1001.Penalties include up to $250,000 in fines and up to five years of imprisonment.

⊙ *I Agree

Date : 08/31/2012

***Name :** Test Name

***Title :** Test Title

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Get Help

Back | Save & Exit | Continue | Cancel & Start Again

SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

Each facility intended to be printed on the certificate must have a corresponding Exporter/'s Certification Statement (ECS). Please upload the ECS to the corresponding facility. You will not be able to submit the application without the ECS for each facility.

If you do not have the ECS, click on the "Save & Exit" button and return to the application when you have the necessary documentation.

NOTE: The ECS attachment cannot exceed 50MB (Megabytes).
The total file size of all ECS attachments cannot exceed 50MB (Megabytes).
The accepted file formats include pdf, bmp, jpeg, gif, png, tiff, doc, and docx.

Name of the Distributor(s)	
*RICK'S MEDICAL DEVICE FIRM(510k)	Upload

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Back | Save & Exit | Continue
Cancel & Start Again

SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

Each facility intended to be printed on the certificate must have a corresponding Exporter/'s Certification Statement (ECS). Please upload the ECS to the corresponding facility. You will not be able to submit the application without the ECS for each facility.

If you do not have the ECS, click on the "Save & Exit" button and return to the application when you have the necessary documentation.

NOTE: The ECS attachment cannot exceed 50MB (Megabytes).
The total file size of all ECS attachments cannot exceed 50MB (Megabytes).
The accepted file formats include pdf, bmp, jpeg, gif, png, tiff, doc, and docx.

Name of the Distributor(s)	
*RICK'S MEDICAL DEVICE FIRM(510k)	1346441380299_162-8-2012_cert.pdf Remove

Back | Save & Exit | Continue
Cancel & Start Again

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Get Help

Please review your application. If all information is correct, click the **Submit** button below. To make changes to a section, click the **Edit** button for that section.

Date: 08/31/2012

Created Date: 08/31/2012 Certificate Type: Certificate to Foreign Government (CFG)

SECTION 1 REQUESTOR INFORMATION — EDIT

Name :Mr. Vijay Maringanti Firm : gnsi		Address : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852	
Telephone number : 301-4656565	FAX Number :	Firm Tax ID code : 12 - 1211111	Email address : vijayasarathi.maringanti@fda.hhs.gov

SECTION 2 MANUFACTURER INFORMATION — EDIT

Firm : GNSI - Class I Exempt Only With Inspection	**Address (P.O. Box not acceptable):** 311 W Side Dr Apt 301 , Gaithersburg , Maryland UNITED STATES , 20878
Registration number :	
License number :	**Date of Last FDA inspection :** 03/01/2011

Firm : RICK'S MEDICAL DEVICE FIRM(510k)	**Address (P.O. Box not acceptable) :** 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number : 786898	
License number (if applicable) :	**Date of Last FDA inspection :**

SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE) — EDIT

Firm : RICK'S MEDICAL DEVICE FIRM(510k)	**Address (P.O. Box not acceptable) :** 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number : 786898	

SECTION 4 PRODUCT INFORMATION — EDIT

Will you be listing any refurbished or remanufactured products in this certificate? (•) Yes ( ) No

Are you the original manufacturer of this product(s)? ( ) Yes (•) No

This product(s) cannot be included on this application

Trade name tn1	**Proper name** pn1

Marketing Status Exempt

Trade name Trade Name2	**Proper name** Proper Name2
Marketing status K991735	
Trade name Trade Name3	**Proper name** Proper Name3
Marketing status K974749	

SECTION 5 WAS THE PRODUCT EVER RECALLED? EDIT

If "Yes" State the recall number and close-out date	Recall Number	Close-out Date :
☑ Yes ☐ NO	Z-1039-05	
Trade name tn1	**Proper name** pn1	
Close-out Letter details :		

☐ Yes ☑ NO		
Trade name Trade Name2	**Proper name** Proper Name2	
☐ Yes ☑ NO		
Trade name Trade Name3	**Proper name** Proper Name3	

SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED EDIT

AFGHANISTAN ALAND ISLANDS	

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE EDIT

Manufacturer	Header Name	SubHeader Name
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As
Distributor	**Header Name**	**SubHeader Name**
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Distributor	Manufactured For

Products Grouping	
Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo noteched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER	RICK'S MEDICAL DEVICE FIRM(510k)-786898(Manufacturer)

Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L Raspatories , FREER , 18.5 cm C.S. Mirror #4 C.S. Mirror #4 12 pack C.S. Mirror #5 C.S. Mirror #5 12 Pack Gracey Deep Pocket 1-2 xp 3/8" Resin Gracey Deep Pocket 1-2 xp 3/8" Stainless Gracey Deep Pocket 3-4 xp 3/8" Resin Gracey Deep Pocket 3-4 xp 3/8" Stainless Cassette SL5 (5 Instr) Cassette SL5 (7 Instr - no rack) Cassette 108(8 Instr) Cassette 108 utility (8 Instr) Cassette 108 Removable Rack(8-16 Instr) Cassette 109 W/12 Slots	

Probe 1 Yellow 7/32" stainless Probe 1 Yellow 3/8 " Resin Probe 12 Yellow 7/32 " Resin Probe 12 Yellow 7/32 " Stainless Explorer 23 (SE) 3/8" Resin Explorer 2 (DE) 3/8" Resin Explorer 3 (SE) 7/32" Stainless Curette Columbia 12-14 xp 3/8" Resin Curette Columbia 12-14 xp 3/8" Stainless Curette Columbia 12-14 xp 7/32" Resin Waxing PKT 1 1/4" Stainless	RICK'S MEDICAL DEVICE FIRM(510k)-786898(Manufacturer) RICK'S MEDICAL DEVICE FIRM(510k)-786898(Distributor)

SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE? EDIT

***(Note :** CDRH does not list a specific country on a certificate.)*

Should the country destination be listed on the certificate ? ○ Yes ◉ No

Indicate the total number of certificates requested: 12

9SECTION 9 EXPORTER'S CERTIFICATION STATEMENT EDIT

The undersigned verifies that all ingredients are approved for use by FDA or appear on the GRAS list, and each product is intended for human consumption and is available for sale in the U.S. without restriction.

Primary Facility : RICK'S MEDICAL DEVICE FIRM(510k) - Manufacturer

Name: Test Name

Title: Test Title

◉ I Agree Date: 08/31/2012

RICK'S MEDICAL DEVICE FIRM(510k) 1346441380299_162-8-2012_cert.pdf

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. . . . . ENTER APPLICATION SUCCESSFUL! . . . . . .

Your Application Number is 337-8-2012

Please keep the Application number for your records. The Application number is required for all communications with FDA regarding this application. Please refer to the help section for more details.

Note: Processing the application will not begin until a complete request package has been received.

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Date : 08/31/2012

Created Date: 08/31/2012

Certificate Type : Certificate to Foreign Government (CFG)

Application Number : 337-8-2012

Application Status : Received

SECTION 1 REQUESTOR INFORMATION

Name :Mr. Vijay Maringanti Firm : gnsi		Address : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852	
Telephone Number : 301-4656565	FAX Number:	Firm Tax ID code: 12 - 1211111	Email address: vijayasarathi.maringanti@fda.hhs.gov

SECTION 2 MANUFACTURER INFORMATION

Firm: GNSI - Class I Exempt Only With Inspection	**Address (P.O. Box not acceptable):** 311 W Side Dr Apt 301 , Gaithersburg , Maryland UNITED STATES , 20878
Registration number:	
License number (if applicable):	**Date of Last FDA inspection:** 03/01/2011

SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

Firm: RICK'S MEDICAL DEVICE FIRM(510k)	**Address (P.O. Box not acceptable:** 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number: 786898	

SECTION 4 PRODUCT INFORMATION

Will you be listing any refurbished or remanufactured products in this certificate? (•) Yes ( ) No

Are you the original manufacturer of this product(s)? ( ) Yes (•) No

This product(s) cannot be included on this application

Trade name tn1	**Proper name** pn1
Marketing status Exempt	

Trade name Trade Name3	**Proper name** Proper Name3
Marketing status K974749	

Trade name Trade Name2	**Proper name** Proper Name2
Marketing status K991735	

SECTION 5 WAS THE PRODUCT EVER RECALLED?

If "Yes" State the recall number and close-out date	Recall number	Close-out Date:
☑ Yes ☐ NO	Z-1039-05	
Trade name tn1	**Proper name** pn1	
Close-out Letter details :		
☐ Yes ☑ NO		
Trade name Trade Name3	**Proper name** Proper Name3	
☐ Yes ☑ NO		
Trade name Trade Name2	**Proper name** Proper Name2	

SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED

ALAND ISLANDS AFGHANISTAN	

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Manufacturer	**Header Name**	**SubHeader Name**
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As
Distributor	**Header Name**	**SubHeader Name**
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Distributor	Manufactured For

Products Grouping	
Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo noteched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L	RICK'S MEDICAL DEVICE FIRM(510k)-786898 (Manufacturer)

Raspatories , FREER , 18.5 cm C.S. Mirror #4 C.S. Mirror #4 12 pack C.S. Mirror #5 C.S. Mirror #5 12 Pack Gracey Deep Pocket 1-2 xp 3/8" Resin Gracey Deep Pocket 1-2 xp 3/8" Stainless Gracey Deep Pocket 3-4 xp 3/8" Resin Gracey Deep Pocket 3-4 xp 3/8" Stainless Cassette SL5 (5 Instr) Cassette SL5 (7 Instr - no rack) Cassette 108(8 Instr) Cassette 108 utility (8 Instr) Cassette 108 Removable Rack(8-16 Instr) Cassette 109 W/12 Slots	

Probe 1 Yellow 7/32" stainless Probe 1 Yellow 3/8 " Resin Probe 12 Yellow 7/32 " Resin Probe 12 Yellow 7/32 " Stainless Explorer 23 (SE) 3/8" Resin Explorer 2 (DE) 3/8" Resin Explorer 3 (SE) 7/32" Stainless Curette Columbia 12-14 xp 3/8" Resin Curette Columbia 12-14 xp 3/8" Stainless Curette Columbia 12-14 xp 7/32" Resin Waxing PKT 1 1/4" Stainless	RICK'S MEDICAL DEVICE FIRM(510k)-786898 (Manufacturer) RICK'S MEDICAL DEVICE FIRM(510k)-786898 (Distributor)

SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE?

***(Note :** CDRH does not list a specific country on a certificate.)*

Should the country destination be listed on the certificate? ○ Yes ◉ No

Indicate the total number of certificates requested: 12

9SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

The undersigned verifies that all ingredients are approved for use by FDA or appear on the GRAS list, and each product is intended for human consumption and is available for sale in the U.S. without restriction.

Primary facility: RICK'S MEDICAL DEVICE FIRM(510k)-Manufacturer

Name: Test Name

Title: Test Title

◉ I Agree Date: 08/31/2012

RICK'S MEDICAL DEVICE FIRM(510k) 1346441380299_162-8-2012_cert.pdf

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SEARCH APPLICATION

APPLICATION NUMBER:		
REGISTRATION NUMBER:		
OWNER OPERATOR NUMBER:		
FACILITY NAME		Manufacturer
ADDRESS, LINE 1:		
ADDRESS, LINE 2:		
CITY:		
STATE / PROVINCE /TERRITORY:	Click here to select a State / Province / Territory	
ZIP:		
COUNTRY/AREA:	--Please select Country--	
APPLICATION STATUS:	Received	

>> Reset >> Submit

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SEARCH APPLICATIONS - SEARCH RESULTS

Search Results - **Total Applications: 1**

The following Applications match your search criteria. You can use the up and down arrows to sort the application list.

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	Application Number	Date Of Application	Status	Certificate Type
○	337-8-2012	2012-08-31 15:30:31.0	Received	Certificate to Foreign Government (CFG)

» Modify Application

« Back » New Search

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Please select from the following options

***Modify Options :**

- ○ Update Recall Close-out Letter / ECS Document
- ○ Update the number of Certificates
- ○ Cancel the application

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Get Help

Please select from the following options

***Modify Options :**

Update Recall Close-out Letter / ECS Document

Update the number of Certificates

Cancel the application

Back to Main | Continue

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Select	Application Number	Date of Application	Certificate Type	Status
⊙	337-8-2012	08/31/2012	Certificate to Foreign Government (CFG)	Return for Action

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CECATS CDRH Export Certificate Application and Tracking System

Get Help

Please review your application. If all information is correct, click the **Submit** button below. To make changes to a section, click the **Edit** button for that section.

Date: 08/31/2012

Created Date: 08/31/2012

Certificate Type : Certificate to Foreign Government (CFG)

Application Number : 337-8-2012

Application Status : Return for Action

SECTION 1 REQUESTOR INFORMATION

Name :Mr. Vijay Maringanti		Address : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852	
Firm : gnsi			
Telephone number : 301-4656565	FAX Number :	Firm Tax ID code : 12 - 1211111	Email address : vijayasarathi.maringanti@fda.hhs.gov

SECTION 2 MANUFACTURER INFORMATION

Firm: GNSI - Class I Exempt Only With Inspection	**Address (P.O Box not acceptable):** 311 W Side Dr Apt 301 , Gaithersburg , Maryland UNITED STATES , 20878
Registration number:	
License number (if applicable):	**Date of Last FDA inspection:** 03/01/2011

SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

Firm: RICK'S MEDICAL DEVICE FIRM(510k)	**Address (P.O. Box not acceptable):** 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number: 786898	

SECTION 4 PRODUCT INFORMATION

Will you be listing any refurbished or remanufactured products in this certificate? ○ Yes ○ No

Are you the original manufacturer of this product(s)? ○ Yes ◉ No

This product(s) cannot be included on this application

Trade name tn1	**Proper name** pn1
Marketing status Exempt	

SECTION 5 WAS THE PRODUCT EVER RECALLED? EDIT

If "Yes" State the recall number and close-out date	Recall Number	Close-out Date:
☑ Yes ☐ NO	Z-1039-05	
Close-out Letter details :		

SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED

AFGHANISTAN ALAND ISLANDS	

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Manufacturer	**Header Name**	**SubHeader Name**
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As
Distributor	**Header Name**	**SubHeader Name**
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Distributor	Manufactured For

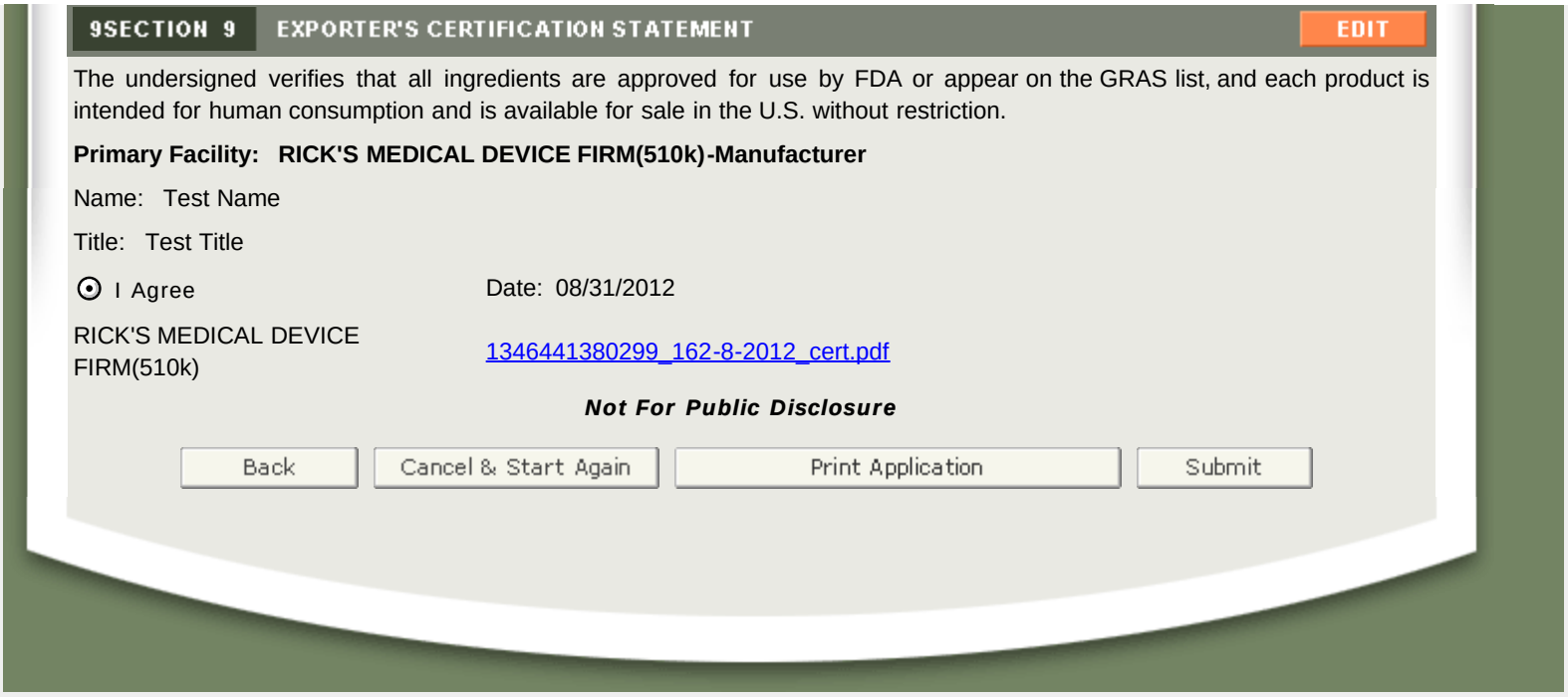
Products Grouping	
Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo noteched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L Raspatories , FREER , 18.5 cm C.S. Mirror #4 C.S. Mirror #4 12 pack C.S. Mirror #5 C.S. Mirror #5 12 Pack Gracey Deep Pocket 1-2 xp 3/8" Resin Gracey Deep Pocket 1-2 xp 3/8" Stainless Gracey Deep Pocket 3-4 xp 3/8" Resin Gracey Deep Pocket 3-4 xp 3/8" Stainless Cassette SL5 (5 Instr) Cassette SL5 (7 Instr - no rack) Cassette 108(8 Instr) Cassette 108 utility (8 Instr) Cassette 108 Removable Rack(8-16 Instr) Cassette 109 W/12 Slots	RICK'S MEDICAL DEVICE FIRM(510k)-786898 (Manufacturer)

SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE?

***(Note :** CDRH does not list a specific country on a certificate.)*

Should the country destination be listed on the certificate ? ○ Yes ◉ No

Indicate the total number of certificates requested: 12



9SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

EDIT

The undersigned verifies that all ingredients are approved for use by FDA or appear on the GRAS list, and each product is intended for human consumption and is available for sale in the U.S. without restriction.

Primary Facility: RICK'S MEDICAL DEVICE FIRM(510k)-Manufacturer

Name: Test Name

Title: Test Title

◉ I Agree

Date: 08/31/2012

RICK'S MEDICAL DEVICE FIRM(510k)

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SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

Each facility intended to be printed on the certificate must have a corresponding Exporter/'s Certification Statement (ECS). Please upload the ECS to the corresponding facility. You will not be able to submit the application without the ECS for each facility.

If you do not have the ECS, click on the "Save & Exit" button and return to the application when you have the necessary documentation.

NOTE: The ECS attachment cannot exceed 50MB (Megabytes).
The total file size of all ECS attachments cannot exceed 50MB (Megabytes).
The accepted file formats include pdf, bmp, jpeg, gif, png, tiff, doc, and docx.

Name of the Manufacturer(s)	
RICK'S MEDICAL DEVICE FIRM(510k)	Upload

Name of the Distributor(s)	
*RICK'S MEDICAL DEVICE FIRM(510k)	1346441380299_162-8-2012_cert.pdf Remove

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The Application Number 337-8-2012 is modified successfully

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Please select from the following options

***Modify Options :**

- ○ Update Recall Close-out Letter / ECS Document
- ◉ Update the number of Certificates
- ○ Cancel the application

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Select	Application Number	Date of Application	Certificate Type	Status
⊙	337-8-2012	08/31/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	317-8-2012	08/29/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	221-8-2012	08/19/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	262-8-2012	08/22/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	225-8-2012	08/20/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	213-8-2012	08/16/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	331-8-2012	08/31/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	311-8-2012	08/29/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	238-8-2012	08/20/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	288-8-2012	08/30/2012	Certificate to Foreign Government (CFG)	Ready for Review

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Please review your application. If all information is correct, click the **Submit** button below. To make changes to a section, click the **Edit** button for that section.

Date: 08/31/2012

Created Date: 08/31/2012

Certificate Type : Certificate to Foreign Government (CFG)

Application Number : 337-8-2012

Application Status : Ready for Review

SECTION 1 REQUESTOR INFORMATION

Name :Mr. Vijay Maringanti		Address : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852	
Firm : gnsi			
Telephone number : 301-4656565	FAX Number :	Firm Tax ID code : 12 - 1211111	Email address : vijayasarathi.maringanti@fda.hhs.gov

SECTION 2 MANUFACTURER INFORMATION

Firm: RICK'S MEDICAL DEVICE FIRM(510k)	**Address (P.O Box not acceptable):** 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number: 786898	
License number (if applicable):	**Date of Last FDA inspection:**

SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

Firm: RICK'S MEDICAL DEVICE FIRM(510k)	**Address (P.O. Box not acceptable):** 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number: 786898	

SECTION 4 PRODUCT INFORMATION

Will you be listing any refurbished or remanufactured products in this certificate? ○ Yes ○ No

Are you the original manufacturer of this product(s)? ○ Yes ◉ No

This product(s) cannot be included on this application

Trade name Trade Name3	**Proper name** Proper Name3
Marketing status K974749	

SECTION 5 WAS THE PRODUCT EVER RECALLED?

If "Yes" State the recall number and close-out date	Recall Number	Close-out Date:
☐ Yes ☑ NO		

SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED

ALAND ISLANDS AFGHANISTAN	

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Manufacturer	**Header Name**	**SubHeader Name**
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As
Distributor	**Header Name**	**SubHeader Name**
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Distributor	Manufactured For

Products Grouping	
Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo noteched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L Raspatories , FREER , 18.5 cm C.S. Mirror #4 C.S. Mirror #4 12 pack C.S. Mirror #5 C.S. Mirror #5 12 Pack Gracey Deep Pocket 1-2 xp 3/8" Resin Gracey Deep Pocket 1-2 xp 3/8" Stainless Gracey Deep Pocket 3-4 xp 3/8" Resin Gracey Deep Pocket 3-4 xp 3/8" Stainless Cassette SL5 (5 Instr) Cassette SL5 (7 Instr - no rack) Cassette 108(8 Instr) Cassette 108 utility (8 Instr) Cassette 108 Removable Rack(8-16 Instr) Cassette 109 W/12 Slots	RICK'S MEDICAL DEVICE FIRM(510k)-786898 (Manufacturer)

SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE? EDIT

***(Note :** CDRH does not list a specific country on a certificate.)*

Should the country destination be listed on the certificate ? ○ Yes ⊙ No

Indicate the total number of certificates requested: 12

9SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

The undersigned verifies that all ingredients are approved for use by FDA or appear on the GRAS list, and each product is intended for human consumption and is available for sale in the U.S. without restriction.

Primary Facility: RICK'S MEDICAL DEVICE FIRM(510k)-Manufacturer

Name: Test Name

Title: Test Title

⊙ I Agree

Date: 08/31/2012

RICK'S MEDICAL DEVICE FIRM(510k)

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SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE?

(Note : CDRH does not list a specific country on a certificate.)

Should the country destination be listed on the certificate ? ○ Yes ◉ No

Indicate the total number of certificates requested : 18

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Please review your application. If all information is correct, click the **Submit** button below. To make changes to a section, click the **Edit** button for that section.

Date: 08/31/2012

Created Date: 08/31/2012

Certificate Type : Certificate to Foreign Government (CFG)

Application Number : 337-8-2012

Application Status : Ready for Review

SECTION 1 REQUESTOR INFORMATION

Name :Mr. Vijay Maringanti		Address : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852	
Firm : gnsi			
Telephone number : 301-4656565	FAX Number :	Firm Tax ID code : 12 - 1211111	Email address : vijayasarathi.maringanti@fda.hhs.gov

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Registration number: 786898	
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Firm: RICK'S MEDICAL DEVICE FIRM(510k)	**Address (P.O. Box not acceptable):** 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number: 786898	

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Are you the original manufacturer of this product(s)? ○ Yes ◉ No

This product(s) cannot be included on this application

Trade name Trade Name3	**Proper name** Proper Name3
Marketing status K974749	

SECTION 5 WAS THE PRODUCT EVER RECALLED?

If "Yes" State the recall number and close-out date	Recall Number	Close-out Date:
☐ Yes ☑ NO		

SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED

ALAND ISLANDS AFGHANISTAN	

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Manufacturer	**Header Name**	**SubHeader Name**
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As
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SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE? EDIT

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Name: Test Name

Title: Test Title

◉ I Agree

Date: 08/31/2012

RICK'S MEDICAL DEVICE FIRM(510k)

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***Modify Options :**

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- ○ Update the number of Certificates
- ◉ Cancel the application

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Select	Application Number	Date of Application	Certificate Type	Status
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○	221-8-2012	08/19/2012	Certificate to Foreign Government (CFG)	Ready for Review
◉	337-8-2012	08/31/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	262-8-2012	08/22/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	317-8-2012	08/29/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	331-8-2012	08/31/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	238-8-2012	08/20/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	225-8-2012	08/20/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	288-8-2012	08/30/2012	Certificate to Foreign Government (CFG)	Ready for Review
○	213-8-2012	08/16/2012	Certificate to Foreign Government (CFG)	Ready for Review

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The selected application will be cancelled.Do you wish to continue?

Cancel Continue

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The Application Number 337-8-2012 is cancelled successfully

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