Prince Sterilization Services, LLC
45 US 46, Ste 602 Pine Brook, New Jersey 07058
Phone: (888) 774-6230 ▪ www.princesterilization.com

| FDA Registered ▪ ISO 13485 Certified ▪ cGMP Compliant |

CUSTOM QUOTE REQUEST FORM

Completion of this form is required to ensure proper service. Please return this sheet with any additional special requirements to Kristah Kohan; kkohan@princesterilization.com: Phone: 888-774-6230

I. Sponsor Contact Information:

Company:		Contact:	
Address:		Telephone:	
Fax:		E-mail:	

Are you a new customer? ☐ Yes ☐ No

II. Information Request:

Prince offers a variety of products and services. To ensure your request is handled as accurately as possible, please fill out the below information in detail.

Please Provide Container or Component Information – One product per form				
Product (Part/Cat) #	**Description**	**Size**	**Qty.**	**Frequency**
Are there any temperature restrictions on the product?			☐ Yes ☐ No	
Who will supply the raw material?			☐ PRINCE ☐ Customer	
Is the end use an injectable / implantable?			☐ Yes ☐ No	

Attn: With the return of this form please attach any vial/bottle drawing and specification sheets that can assist us in determining load size/packaging requirements. If available, please provide a web link to the catalog link or picture of the material needed for this request.

III. Processing Options:

Select	**Rinse/Cleaning**	**Select**	**Depyrogenation/Sterilization**
☐	Water for injection (WFI) rinse[1]	☐	Depyrogenation via heat[2]
☐	WFI rinse/Detergent rinse (CIP-100/300)	☐	Dry heat sterilization[2]
☐	Total Organic Carbon (TOC) Detergent removal confirmation	☐	Depyrogenation via washing
List specifications, if applicable		☐	Autoclave (moist heat steam)[3]
		List specifications, if applicable	

[1] Prince's WFI complies with EP/USP WFI testing requirements. Our standard rinsing/cleaning service consists of three rinses performed in an ISO-7 clean room.
[2] Depyrogenation and dry heat sterilization are performed in an ISO-7 cleanroom using our GMP, ISO-5 oven with HEPA filtered air.
[3] Steam sterilization is performed in our ISO-7 cleanroom using either of our GMP sterilizers fed with clean pure steam generated from WFI or with purified water.

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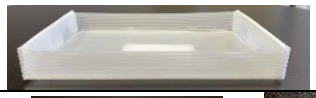
IV. Packaging Options, Vials & Containers

Vials & Containers						
Select	**Tray Selection/Presentation**	**Representative Example of Tray/Pouch Material**				
☐	Stainless steel (316L) – 4-sided					
☐	Polypropylene- 4-sided					
☐	Autoclavable[4] pouch Best for product that requires terminal sterilization.	 				
☐	Nonpermeable[5] pouch Applicable for product where aseptic packaging is satisfactory.					
Primary Barrier						
☐	Autoclavable pouch[4]	  				
☐	Nonpermeable pouch[5]	 				
☐	Not Applicable					
Secondary Barrier		**Tertiary Barrier**		**Fourth Barrier**		☐ **Additional Pouch/Barrier Request:** Specify Requirements:
☐	Autoclavable pouch[4]	☐	Autoclavable pouch[4]	☐ Nonpermeable pouch[5]		
☐	Nonpermeable pouch[5]	☐	Nonpermeable pouch[5]			
☐	Not Applicable	☐	Not Applicable	☐	Not Applicable	
If a tray configuration was selected, please select one option;				☐ vials upright		☐ vials inverted

[4]High quality permeable Tyvek®/HDPE pouches designed for steam sterilization. Vacuum cannot be pulled directly on autoclave pouches. These should not be sprayed with clean room disinfectants.
[5]High quality sterile non-permeable barrier. A vacuum will be pulled on all non-permeable pouch layers unless otherwise specified. Compatible with cleanroom disinfectants for proper material staging.

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V. Packaging Options, Closures, Stoppers, & Related

Closures, Stoppers, & Related					
Select	**Standard Configuration**				
☐	Material is washed or preprocessed as specified above. Material is transferred into 2x autoclavable pouches (primary & secondary barrier) and moist heat steam processed. The steam processed material is then further packaged in 1x nonpermeable bag (tertiary barrier) for three total packaging barriers. A light vacuum may be applied.				
Custom Configuration Requests					
Primary Barrier		**Representative Example of Tray/Pouch Material**			
☐	Autoclavable pouch[4]				
☐	Not Applicable				
Secondary Barrier		**Tertiary Barrier**		**Fourth Barrier**	
☐	Autoclavable pouch[4]	☐	Autoclavable pouch[4]	☐ Nonpermeable pouch[5]	
☐	Nonpermeable pouch[5]	☐	Nonpermeable pouch[5]		
☐	Not Applicable	☐	Not Applicable	☐	Not Applicable
☐	**Additional Pouch/Barrier Request:** Specify Requirements:				

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VI. Ancillary Services

Is a validated process required? ☐Yes[6] ☐No **Is an expiration date required?** ☐Yes[6] ☐No

VII. Laboratory Services

Analytical/Laboratory Certificate Requirements		
Select	**Test**	**Certificate Applicability**
☐	CoA – USP <788> - Low Particulates	Laboratory testing certificates generated for product release/cycle conformance if necessary.
☐	CoA – USP <85> - Endotoxin	
☐	CoA – USP <71> - Sterility	
☐	CoA – TOC - Total Organic Carbon	
☐	CoP Certificate of Processing	Certificate for material that was steam or dry heat processed with no validation.
☐	CoS Certificate of Sterilization	Certificate for material that was processed in accordance to a validated sterilization process.
☐	CoD Certificate of Depyrogenation	Certificate for material that was processed in accordance to a validated depyrogenation process.
☐	**Additional Request** Specify Requirements:	

Notes:
Please attach and return additional specifications. Lead times for custom products are dependent upon quantity, analytical requirements, and availability of materials.

This form is required to be filled out in full so that an accurate quote may be prepared. All information exchanged between "PRINCE" and the above "Company" is considered to be Confidential. PRINCE will not be responsible for failure by the customer to request any other requirement not included on this sheet.

Signed: _____ Date: _____

[6] A technical services representative from PRINCE will reach out to you upon receipt of this form.