



MEDICAL, HEALTH, AND WELLNESS PRODUCTS: CUSTOMER REQUIREMENTS

We ask that you please fill out this form and submit it to your sales representative at the time of RFQ.

Thank you for your assistance in making sure we continue to provide the best possible service in adherence with our Quality Policy and ISO standards

Date _____

CONTACT INFORMATION

Company Name: _____

Primary Quality Contact Name: _____ Title: _____

Phone: _____ Email: _____

PRODUCT

Part Number(s) _____

Which of the following best describes the product or family of products that JBC is making for you?

_____ component(s) or _____ finished device(s)

Please provide a general description of the device or component that JBC is making for you.

What is the intended use or purpose of the finished device?

Is or will the finished device be registered with the FDA? Yes No

If yes, what class? Class 1 Class 2 Class 3 N/A

Will the finished device be available outside of the United States? Yes No

If JBC is manufacturing the finished device, please send a list of all countries where the device will be sold.

Please list any applicable regulatory requirements that we need to be aware of.

Do you have any specifications for the product (Please check all that apply and attach relevant documents)

Print CAD Drawing Material Spec Sheets Supplier Quality Manual Other

PROCESS

Do you have any specifications for the manufacturing process?

Clean room requirements Yes No If yes, what class?

Will the part undergo post-process sterilization after it leaves JBC Technologies? Yes No

Please document your cleanliness specifications here. Be as detailed as possible.



MATERIALS HANDLING

Do you have any specific labeling, packaging, storage, or handling requirements for this product? Yes No

If yes, please provide details here:

Labeling:

Packaging:

Storage:

Handling:

QUALITY

Please list any specific requirements for measuring and monitoring

SUBMIT

Please submit this form along with any detailed requirements to your sales representative at the time of RFQ. We also request that you copy our quality department at jbcquality@jbc-tech.com.

FOR INTERNAL USE ONLY

I certify that the information on the form is complete, and the component or device is approved for fabrication under the scope of JBC's medical, health and wellness Quality Operating System.

JBC Technologies acts as a contract manufacturer and does not perform regulatory submissions. The customer (legal manufacturer/design authority) retains full responsibility for regulatory reporting, including complaints, adverse events, MDR, and post-market activities. JBC will provide manufacturing and quality information to support these activities upon request.

Details are defined in MPR.01 and available upon request. By signing below, JBC confirms that these responsibilities have been communicated to the customer.

Sales Representative

Date

Quality Representative

Date

MPR.07.1 Medical Device Customer Requirements Form Rev 2

We Make Doing Business Easy!

www.jbc-tech.com | 440.327.4522

Corporate Headquarters | 7887 Bliss Parkway, North Ridgeville, OH 44039

