



# MEDICAL DEVICE: 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 to our medical customers 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 this product or family of products?

\_\_\_\_\_ component(s) \_\_\_\_\_ finished device(s)

Please provide a general description of the finished medical device/family of devices.

\_\_\_\_\_  
\_\_\_\_\_

What is its intended use or purpose?

\_\_\_\_\_  
\_\_\_\_\_

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?

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](mailto:jbcquality@jbc-tech.com).

MPR.05.1

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