

Medtech Material Application Questionnaire / Design Form



Requested By:

Date Requested:

Date Needed:

Company Information*

Supplier Name:

Supplier Company:

Address:

Phone:

Email:

Customer Information*

Customer Name:

Customer Company:

Division:

Address:

Phone:

Email:

Material Information

Project Name:

Material Trade Name:

Color:

Compound:

Application Classification*

Packaging:

Packaging Type:

Type of Administration:

Oral Type:

Usage Method:

IVD:

FDA Medical Device Classification:

FDA Medical Device Classification,
(please complete): 21 CFR:

Contact Duration:

Nature of Body Contact:

EU MDR Class:

Certification:

Process Information*

Process to Be Used:

If Other:

Region for Production:

In which countries will the
final product be used:

Is the part a medical device according to:

a. FDA (USA) NA Yes No

b. European Medical Device Directive (MDD) NA Yes No

Life cycle of device made
from requested material?

Regulatory Requirements:

Asia Regulatory: List Below:

Application Information*

Application

Product End Use

Contact Type

Drug Form

Duration of Patient Contact

Laser Marking

Laser Marking Depth

Laser Welding

Radiopacity NA Yes No

Antistatic NA Yes No

Barrier Oxygen/Water NA Yes No

UV Vis Blocking NA Yes No

Nucleation NA Yes No

Other

Sterilization NA Yes No

Sterilization Method Used

If Others

¹ If you chose Sterilization type Gamma or
E-Beam, please indicate the total dose:

² If you chose Sterilization type Steam,
please indicate the temp/time:

Critical Requirements

Additional Information / Comments: