EagleMedical
PACKAGING, STERILIZATION, INC.

2921 Union Rd
Paso Robles, CA 93446

Readiness Checklist

1. Product design complete and fixed for edge-critical features and size requirements
    a. Exploded top level device drawing / evaluate for protective features
        i. Nested BOM
    b. Product-specific general description of device & intended use
    c. Biocompatibility study complete
    d. Mechanical performance verification testing complete
    e. Prototype dunnage available for preliminary package testing
    f. If 2-part assembly: mechanical tolerance analysis complete (Cpk=1.25min)
    g. All coatings, finishes, and surface treatments for base components selected/frozen
2. Manufacturing supply-chain stable
    a. Primary manufacturers selected and manufacturing process frozen
    b. Manufacturing residues, types, amount(s), and associated cleaning is defined and in-place
3. PATH Labeling design-data, implementation (data base) schema is defined as follows:
    a. Labeling configuration (location, quantity) for:
        i. Patient record
        ii. Outer pouch
        iii. Box, top/end
        iv. Shipper m-up
    b. IFU labeling written content fully defined for:
        i. Launch country language
        ii. IFU or E-IFU
        iii. Caution(s), warning(s), contraindication(s) fully complete
    c. Customer part number / description data base fully defined as follows:
        i. Label part-numbering schema fully defined with part-number “blocks” available for packaging design drawings
        ii. UDI, numbering schema fully defined
        iii. “REF” / catalog numbering schema fully defined and description / materials
        iv. Black & white customer logo fully complete and ready for digital file export
        v. Handling / storage / distribution requirements defined
            1. Temperature, pressure, relative humidity constraints known, if any
4. If assembly, and/or cleaning processes needed:
    a. Cleaning process validation and procedures complete, or for quote by EMPS (Quote Date, Validation #)
    b. Assembly process, fixtures, tools, validation and procedures complete, or for quote by EMPS
        i. Define customer owned property (fixtures, tooling, etc.)
5. Sterilization Validation Quote (irradiation only)
6. FDA Device Listing information (510K number)

Your signature indicates that you’ve read this document and certifies that your project has completed each of the above milestones

Name:

Title:

Company Name:

×_____

Signature *Date*