laservision

Laser Compliance

Date: **Quotation Number:**

Price: **Terms:**

Customer:

Schedule:

a) Remote design consultation services starting on DATE till completion.

b) (1) day onsite visit to conduct CDRH.

c) CDRH Compliance certificate required prior to DATE.

CDRH Laser Compliance and Consulting Services:

Laservision and the assigned Certified Laser Safety Officer (CLSO) will assist and support COMPANY in the design and development of a Center for Devices and Radiological Health (CDRH) compliant laser system per 21CFR1040.10 Federal Laser Product Performance Standards (FLPPS) that utilizes an embedded Class 4 Keyence laser; preparation of FDA Form 3632 (Guide for Preparing Product Reports for Lasers and Products Containing Lasers) required to receive an accession number for sale, distribution and/or use of laser systems and will review, support and address the following CDRH requirements as applicable. (to the right) >>

COMPANY will Receive:

- Laser Hazard Analysis Report(s) and laser classification calculations for this system based on CDRH accessible emission limits (AEL)
- Recommendations for Engineering Compliance Measures
- Support/assistance writing laser safety practices for user manual if applicable
- Support/assistance submitting final report to CDRH

A preliminary FDA Form 3632 report (i.e. 1st DRAFT) of the laser system including recommendations for the laser system design and/or other required CDRH compliance features will be initiated immediately following an overall project/system review via emails, conference calls, WebEx, etc. CDRH compliance support for this project will continue and be conducted via an ongoing dialogue with COMPANY which will include phone conversations, email messages, exchange of files, CAD drawings, schematics, etc. for the purpose of developing a completed FDA Form 3632 required for CDRH submission.

Subsequent DRAFT reversions/refinements of FDA Form 3632 including supplemental information, drawings and attachments will be labeled sequentially (i.e. 2nd DRAFT, 3rd DRAFT, etc) along with comments, recommendations and open/action items for review and completion until such time as it is mutually agreed that this laser system meets/fulfills all required elements of/and is in full compliance with Federal Laser Product Performance Standards 21CFR1040.10 as applicable.

Quotation prepared by:

_____

Name

Date:

Assigned CLSO:

Quotation accepted by:

_____

Print Name: _____

Date: _____

Requirements

- Laser Classification
- Accessible emission limits (AEL)
- Tests for determination of compliance
- Protective housing
- Safety interlocks
- Remote Interlock connector
- Key control
- Laser radiation emission indicator
- Beam attenuator
- Location of controls
- Viewing optics
- Scanning safeguard
- Labeling requirements
- User information
- Quantitative hazard analysis for laser radiation field(s)
- Technical assistance completing CDRH report form FDA 3632 and attachments

Professional Services Include:

Ongoing consulting time and one-time travel expenses to facility.

Laservision and the assigned CLSO will support and assist Company as necessary during this CDRH regulatory compliance project. However, it is ultimately the responsibility of COMPANY to file the proper paperwork with the CDRH. A purchase order must be included at the time of scheduling the initial onsite system design review and audit.

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