

## What is needed?

In order for the laser machine to be safe and fully approved by FDA regulations, the following stickers must be affixed to the laser machine in designated locations. These stickers provide information as to the serial number of the machine, when the machine was produced or sold, contact information of manufacturer or importing authority, compliance to regulations, and safety warnings.

## Installing laser machine stickers.

The four types of stickers you will need for this installation are the Manufacturer Data, the FDA compliance, Operator Safety, and the Class IV laser radiation stickers. Please read the entire installation guide before applying stickers to the machine.

The first sticker is the manufacturer's data sticker. This sticker gives information about when the machine was built, serial number, and contact information of the manufacturer or importing authority. The manufacturer's data sticker needs to be affixed to the machine on the side or rear of the machine. This sticker must be on the main frame or a portion of the machine that is not removable. Please do NOT place this sticker on a door or panel. We understand that each laser machine may be built similar, but space and placement will vary. The suggested location is the side of the machine above the operator access panel. Please see the picture here as an example.



The second sticker indicates the compliance to the FDA regulations. This sticker expresses the compliance of the laser machine to FDA regulations as set in 21 CFR Subchapter J and detailed in FDA document 1040.10. This sticker should be placed near the manufacturer data sticker. The suggested location for this sticker is directly below the manufacturer's data sticker. Please see the picture here as an example.

The third sticker is the "Operator Safety" sticker. This sticker expresses that the laser machine contains a laser device and the concerns of the laser beam. The laser beam is invisible and even a small portion of the laser beam can cause injury to a person. The laser machine is built as a fully enclosed housing which does not let the laser beam escape. Items inside the laser machine will likely become exposed to the laser beam. The main operator door is equipped with a safety switch that inhibits the laser beam from working if the door is opened. This switch makes the laser machine safe to use in the event the main door is opened while the machine is working with the laser beam on. **Never try to defeat the safety switch!** The "Operator Safety" sticker should be placed on the operator's access door such that the operator intuitively reads the sticker every time the door is opened. Please see the picture here as an example.

The last set of stickers are the "Class IV Laser Radiation" Stickers. The main operator door is used for daily work, but it is sometimes necessary to open access panels in order to perform maintenance of the machine. These stickers remind the operator that a primary component of the machine is the laser device and only a qualified service person should enter the panel. The main power to the laser machine should be disconnected when opening maintenance areas of the laser machine. These stickers need to be located on each access door/panel and near the handle.

Please be safe with any Laser device



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The installation of the Manufacturer Data, the FDA compliance, Operator Safety, and the Class IV laser radiation stickers is a requirement for conforming to FDA regulations. Please sign and return the attached form to indicate that the installation has been completed. Please return the acknowledgment within a reasonable time period.

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I, \_\_\_\_\_, am the owner / controller of the laser machine sold to our company from Scottware.net. I acknowledge that I have completed the installation of the Manufacturer Data, the FDA compliance, Operator Safety, and the Class IV laser radiation stickers for compliance to FDA regulations.

Position: \_\_\_\_\_

Signed: \_\_\_\_\_

Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Company Address: \_\_\_\_\_  
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Mail to :

Scottware.net / FDA Compliance  
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