SUSPICIOUS LASER PRODUCT PROTOCOL (SLaPP)

This form contains a self-directed documentation process which assists in the disposition of laser-based products which appear to be non-compliant.

Person Completing Form/POC	
Organization	
Address	
City, State, Zip	
Phone/FAX/Email	
Product Description	
Model/Stock Number/Serial No	
Manufacturer	
Address	
Phone/FAX/Email	
Purchase Price	
Purchase Date/Delivery Date	
Third Party Assembler/POC	
Organization	
Address	
City, State, Zip	
Phone/FAX/Email	

Upon suspicion of non-compliance and/or safe laser device or product, complete the following steps. POC **must** initial each step, supervisor/manager **must** sign completed form.

STEP ID	TASK	COMPLETED (POC Initials)	NOTES (keep track of call dates/times with vendors)
01	**DEACTIVATE/REMOVE POWER FROM PRODUCT**- This includes physical separation of power cords and batteries from product	_____	
02	**SEQUESTER INTO A SECURE AREA**- Transfer into an area or container and secure with lock.	_____	
03	**CREATE ISOLATED SECURE AREA TO PERFORM TESTS**- Create or isolate a Class IV/4 LCA	_____	
04	**TAKE PICTURES**- Take pictures to document device or product- do so with a scaling element in frame	_____	
04a	**Front** (port aimed camera)	_____	
04b	**Rear** (port aimed away from camera)	_____	
04c	**Top** (port on right side)	_____	
04d	**Side** (port on right side)	_____	
05	**TAKE MEASUREMENTS**- Using appropriate Photometer-based test equipment, and as stipulated by 21CFR1040.10/.11 (e- Tests for determination of compliance) and/or IEC/EN60825 (Section 5- Determination of the accessible emission level and product classification), test emission five (5) times	_____	**EQ** / **Mfg** / **Model** / **Stk #** / **S/N** Meter Sensor

5.01	Test Data Point 01	_____	
5.02	Test Data Point 02	_____	
5.03	Test Data Point 03	_____	
5.04	Test Data Point 04	_____	
5.05	Test Data Point 05	_____	
06	**MAKE DETERMINATION**- Does the product emit what was advertised (and is stated on labeling and documentation)? ☐ YES ☐ NO Are the labels correct and in the proper locations? ☐ YES ☐ NO If BOTH YES, then introduce into organization with the proper tracking and cognizance (supervisor/manager signature in Notes section). If not, continue to 07 below.	_____	
07	**NOTIFY THIRD PARTY ASSEMBLER, DISTRIBUTOR AND/OR VENDOR**- Let the assembler/distributor/vendor know the product, as you have determined, is NOT compliant to US and/or EU standards. Do they have an accession number? ☐ YES ☐ NO If YES (record in Notes), will they take the product back and correct the issues? ☐ YES ☐ NO If BOTH YES, then return to vendor. If not, continue to 08 below. *(it may be possible that installation results in a modification of the original product under 21CFR1040.10(i).)*	_____	
08	**ALERT APPROPRIATE AGENCIES**- Contact the appropriate federal, state, and local authorities	_____	
8.01	(FDA-CDRH)		

PHONE	800-638-2041
EMAIL	radhealthcustomerservice@fda.hhs.gov
MAIL	U.S. Food and Drug Administration Center for Devices and Radiological Health Document Mail Center – WO66-G609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002
Both EMAIL and MAIL	Submit with header on a letter containing the form or a cover sheet may include: "Laser Products Trade Complaint – Please forward to the Branch Chief for Magnetic Resonance and Electronic Products in OIR/DRH"
NOTE	An assessment of the laser product should be made to the rest of the FDA general and laser performance standard (21CFR1010; 1040.10(f), (g), (h), and (i); & 1040.11. Alternatively, IEC 60825-1, Edition 2 may be used as per LN 50: http://www.fda.gov/downloads/MedicalDevices/.../ucm094366.pdf)

8.02	(State/Local)-Contact specific state and/or local authorities as necessary. **PHONE** **EMAIL** **MAIL**	_____	
09	**DETERMINE DISPOSITION**- Discuss state of compliance with all stakeholders involved with its selection, acquisition, and use.	_____	
9.01	If it is determined the product is non-compliant and/or unsafe (and manufacturer will not make compliant), It will be used under specific circumstances, and a permanent label bearing the words “THIS PRODUCT IS NON-COMPLIANT WITH US AND INTERNATIONAL STANDARDS, WILL NOT LEAVE THIS FACILITY, AND NOT BE INTRODUCED INTO COMMERCE” shall be applied on a prominent surface in a position such that it does not expose the reader to the emission of the laser.	_____	
9.02	Review and determine if any action is required as per 21CFR1003 (Notification of Defects or Failure to Comply) and/or 21CFR1004 (Repurchase, Repairs, Or Replacement of Electronics Products). If so, coordinate with any/all stakeholders.	_____	
10	**NOTE DECISION AND DISPOSITION**- In order to ensure a complete process, note final disposition in note field, attach communications (email, physical letter) or note who, date, time)	_____	

LSO

_____ _____
Signature Date

_____
Print Name

Supervisor/Manager

_____ _____
Signature Date

_____
Print Name