

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax: (301) 594-4715 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 04/20/2015 - 04/22/2015
	FIR NUMBER 3002808127

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Masakazu Nakajo, Executive Officer

FIRM NAME FujiFilm Optics Co. Ltd. - Sano Factory	STREET ADDRESS 700 Konaka-cho
CITY, STATE, ZIP CODE, COUNTRY Sano-City, Tochigi 327-0001, Japan	TYPE ESTABLISHMENT INSPECTED Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

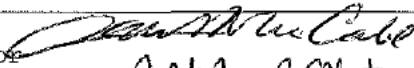
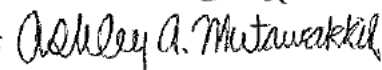
Specifically,

- A. Your firm utilized process parameters for routine laser welding processing which were not validated. Your firm validated the operating parameters of (b) (4) but different operating parameters can be used as well. In addition, you do not have a documented statistical rationale for the sample size selected.
- B. Your firm did not validate one of your routine (b) (4) sterilization cycles which includes sterilizing the (b) (4) (marketed in the United States) in combination with other accessories (b) (4) during the same cycle.
- C. Your firm did not determine the worst case materials that make up the overtube accessory used in U.S. marketed endoscopes (models: EN-450P5, EN-450T5, and EC-450BI5) and you did not segregate/test them for Ethylene Oxide/Ethylene Chlorohydrin (ECH) residues.

OBSERVATION 2

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been established.

Specifically, your firm has not conduct a test method validation for the (b) (4) testing and (b) (4) testing procedures implemented in October 2009 and December 2010, respectively. These procedures are utilized for testing the firm's accessories (b) (4) marketed in the United States) which receive EO sterilization.

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OBSERVATION 3

Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically, your firm is not following your procedure (b)(4) *Nonconforming Product Control Standard* which requires the analysis of nonconformities. Investigations are either not documented or are only documented as the test performed to confirm the nonconformity (i.e. Visual Inspection). For example:

A. Nonconformity designated (b)(4) number (b)(4) for (b)(4) did not have the investigation documented. Your verbal explanation of the investigation included (b)(4) This quality data was not printed, recorded, or documented as transcribed from the screen.

B. Nonconformities designated as (b)(4) number (b)(4) for (b)(4) had no documentation of analysis.

C. Nonconformity designated as (b)(4) number (b)(4) for (b)(4) (b)(4) (b)(4), and (b)(4); and (b)(4) number (b)(4) only had "visual inspection" documented for the investigation.

D. Your firm does not have a documented investigation or documented reason for not investigating non-conformances found during the manufacture of the flexible section assembly which is a sub-assembly of the endoscopes including the duodenoscope ED-530XT. During the review of flexible section assembly batch records including lot's (b)(4), non-conformances were identified, but no investigations were conducted. The batch records lacked a rationale being not conducting an investigation and who approved the lack of investigation.

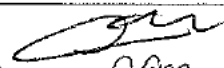

E. Your firm does not have a documented investigation in regards to a biological indicator positive result found during the visual inspections conducted on the (b)(4) (batch lot (b)(4)) EO sterilized in September 2013.

OBSERVATION 4

Procedures for acceptance of incoming product have not been established.

Specifically,

A. Your firm does not have an incoming acceptance activity for the culture media (b)(4) (b)(4) used for conducting bioburden testing of your accessories (including the (b)(4) which is an accessory for U.S. marketed endoscopes model's EN-450P5, EN-450T5, and EC-450BI5) which are EO sterilized. In addition, your firm does not have a procedure in place for periodic growth promotion of

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the media purchased.


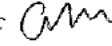
- B. Your firm has not documented critical components in order to establish appropriate testing that shall be conducted. Your firm does not conduct a verification examination and/or inspection (i.e. dimension check) of the supplier's critical component testing of an incoming batch to ensure the results are correct.
- C. Your firm's procedure (b)(4), *Procedure manual on incoming inspection of parts and sub-assembly of medical equipments*, (b)(4), does not require incoming inspections and/or examinations of all critical components used in the production of your endoscopes (i.e. duodenoscopes) at any frequency to ensure they are meeting quality requirements.
- D. Your firm has no written specifications for the distal tip sub-assembly which is a critical component utilized in the manufacture of the duodenoscope model ED-530XT. Your current practice is to review the paperwork received from the supplier. However, there is no incoming examination and/or inspection (i.e. verifying critical dimensions) of the distal tip sub-assembly. Your distal tip sub-assembly component is considered a Level C component which requires dimensional verification on a representative sample quantity of the lot received. However, your firm did not conduct dimensional verification on lot's (b)(4) and (b)(4) dated (b)(4) and (b)(4) respectively, even though it is required per your procedure.
- E. Your firm does have a procedure in place relating to controlling the handling, storage, and prevention of mix-ups for the incoming components prior to being accepted into your inventory. On 04/20/2015, incoming components were observed stored next to released components that were going to be shipped to your sister facility.

OBSERVATION 5

Document control procedures have not been adequately established.

Specifically, your firm did not follow your procedure M4230 (*Medical*) *QMS Document Control Provisions*. For example:

- A. Your firm failed to follow procedure (b)(4) for revisions to current documents. Changes to page (b)(4) of Documents number (b)(4) and (b)(4) which describe parts of the procedure for manufacturing the (b)(4) contain (b)(4) on the master copy of the document. The change control process was not followed to incorporate these changes into the document and photocopies of the master document with the changes written in pencil were distributed to the production floor for use.
- B. Your firm was unable to produce change control documentation showing the creation and approval of procedure (b)(4) effective on September 19, 2011.

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OBSERVATION 6

Procedures for rework of nonconforming product have not been adequately established.

Specifically, your firm follows procedure SZ8300 *Nonconforming Product Control Standard* which includes section (b) (4). This section of the procedure states that (b) (4).
Your firm does not have a "rework procedure manual" but does have procedure (b) (4) *Adjustment Manual of Rejected Goods Revision* effective date 2014.8.27, which contains instructions on information to be documented on forms including but not limited to documenting pertinent information on form (b) (4). Although procedure (b) (4) is currently effective, your firm is not following this procedure and does not document the required information on (b) (4).

OBSERVATION 7

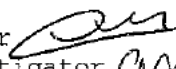
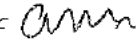
Procedures to ensure equipment is routinely calibrated have not been adequately established.

Specifically,

A). Incubators utilized for (b) (4) as part (b) (4) testing have not been calibrated at a working range or according to the specification temperature ranges set as evidenced by examples including, but not limited to the following:

- (b) (4)
- (b) (4)

B). Your firm does not monitor the incubator temperature during incubation of the media plates utilized for bioburden testing.

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.

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