

April 19, 2013

NOTE TO FILE

SSD CASE: SSD-13-08

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SUBJECT: No checklist was used

No checklist was used because the changes do not involve the safety functions of the device. Changes are limited to adding a new manufacturing location to the registration certificate NR-1234-D-101-E. A Request for Additional Information (RAI) was sent to make sure Thermo Fisher Scientific, Inc. meets the Quality Assurance and device labeling requirements for the new manufacturing location in China.