DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 Fax:(301) 594-4715 Industry Information: www.fda.gov/oc/industry	05/26/2015 - 05/29/2015 FEI NUMBER 3004112148

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Stefan G. O. Miltenyi, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Miltenyi Biotec Gmbh	Friedrich-Ebert-Str 68
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bergisch Gladbach 51429, Germany	Manufacturer; Complaints File Establishment

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 I OBSERVED:

OBSERVATION 1

The written MDR Procedure does not include an internal system which provides for the timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements.

Specifically, your Corporate SOP-MAI-008 does not include review of events that may reportable to the United States FDA. For example, you do not review complaints for reportable malfunctions.

OBSERVATION 2

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, your procedures for complaint handling reporting do not ensure:

A. oral complaints are documented upon receipt;

B. all complaints are entered into the complaints system.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Cynthia T. Cain, Investigator	12/29/2015

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OBSERVATION 3

Records of complaint investigations do not include required information.

Specifically, records of complaint investigations:

A. do not include the date the complaint was received;

B. any reply to complainant.

OBSERVATION 4

Records of complaint investigations are not maintained by the formally designated unit.

Specifically, complaint 1340 was received 03.Sept.2014. As of 28 May 2015, the investigation is not complete and is not documented in the file. The complaint file is still open; it has not been closed

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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.

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