DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US FDA CDRH White Oak Building 66, Room 3540 10903 New Hampshire Ave. Silver Spring, MD 20993 301-796-5819 Industry Information: www.fda.gov/oc/industry	1/16 - 19/2023
	FEI NUMBER 3001278222

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Stefan Ruck, VP Global Quality & Regulatory Affairs

FIRM NAME	STREET ADDRESS
CeramTec GmbH Medical Products Division	CeramTec-Weg 1
CITY, STATE AND ZIP CODE Marktredwitz, Bavaria, Germany D-95615	TYPE OF ESTABLISHMENT INSPECTED Device 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 (I) (WE) OBSERVED

1)A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures. Specifically, the Operational Qualification for process number/3655-05 did not demonstrate the acceptance of the process at the full pressure range. Also, there was no performance qualification made to demonstrate the process reproducibility.

Also, (b)(4) was opened for observed defects on raw ceramic ball head product including (b)(4) (b)(4) Defects were determined to be caused in the (b)(4) process because of inadequate vacuum removal of remaining powder from previous process cycles. (b)(4) does not identify that the powder process is validated and the powder process validation was apparently not reviewed. The Operational Qualification did not establish vacuum strength and vacuum dwell time parameters for the process.

2)Written MDR procedures have not been developed, maintained, and implemented. Specifically, the firm's Adverse Event Procedure/MD-PB-00033 does not include details for making MDR reports to FDA.

1) Promise to correct
2) Promise to correct
24th Jan. 2023

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephen D. Eich, Investigator	01/19/2023