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	10/09 - 12/2023
	FEI NUMBER 3020976354

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Bas Spanjers, Plant Manager

FIRM NAME	STREET ADDRESS
Synergy Health Ede BV	Faunalaan 46
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Venlo, Limburg, Netherlands 5928 RZ	Device Contract Sterilizer

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)Procedures for changes to a process have not been adequately established. Specifically, the process treatment factor for xray sterilization in the Venmo facility was changed from [(b)(4)] reportedly on September 11, 2023. The change was not documented and approved in the change control system.

2)Procedures for monitoring and control of process parameters for a validated process have not been adequately established. Specifically, the conveyor speed in the Xray treatment area has not been adequately defined. Process monitoring is performed at [(b)(4)] According to the operating technician the system allows speed settings between 0 and 4.5 m/minute. The described working range (undocumented) for the conveyor speed is between [(b)(4)].

3)The device history record does not demonstrate that the device was processed in accordance with the device master record. Specifically, the batch record for the processing of UNO 03 GentleCath Glide urethral catheters batch run [(b)(4)] does not include the process treatment (number of laps) for xray processing. The routine irradiation specification shows that the xray process should include 14 process event laps. The customer identification report describes that the product should get [-] laps and [-] pass. The company was able to generate a run report that showed that the product was processed with [-] laps and [-] passes (not found in the DHR).

Annotation

1.) Promised to correct
2.) Promised to correct
3.) Promised to Correct
SSE 10/12/2023

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephen D. Eich, Investigator	10/12/2023