

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 08/14/2017-08/22/2017*
	FEI NUMBER 3011564121

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Ms. Chelsey L. Chandler, Center Manager

FIRM NAME Lincare, Inc. dba United Medical Home Infusion	STREET ADDRESS 1527 South Bowman Road Suite D
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CITY, STATE AND ZIP CODE Little Rock, AR 72211-4200	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products
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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.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

A disinfecting agent is used in the ISO 5 areas that is not sterile. Specifically, your firm utilizes one disinfectant in the ISO 5 areas (b) (4) which is not sterile. This non-sterile disinfectant is utilized on a (b) (4) basis in the firm's (b) (4) laminar airflow hoods ((b) (4)) and (b) (4)

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jason R. Caballero -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jason R. Caballero, Investigator	DATE ISSUED 08/22/2017
	<small>Digitally signed by Jason R. Caballero -S DN: cn=Jason R. Caballero, o=FDA, ou=FDL, email=jcaballero@fda.hhs.gov, c=US Date: 2017.08.22 13:16:55 -0500</small>		

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***DATES OF INSPECTION**

08/14/2017(Mon),08/15/2017(Tue),08/16/2017(Wed),08/17/2017(Thu),08/18/2017(Fri),08/21/2017
(Mon),08/22/2017(Tue),

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Jason R. Caballero, Investigator

DATE ISSUED

08/22/2017