

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 2/3/2026-2/9/2026*	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Gregory T. Kneeland, President		FEI NUMBER 3005831263	
FIRM NAME Dick Medical Supply LLC	STREET ADDRESS 1946 Camaro Ave		
CITY, STATE, ZIP CODE, COUNTRY Columbus, OH 43207-1715	TYPE ESTABLISHMENT INSPECTED 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.			
<i>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.</i>			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Procedures for timely complaint handling have not been documented. Specifically, you have not documented a customer complaint procedure. However, during the current inspection, you provided evidence of receiving customer complaints. Five (5) of the ten (10) customer complaints records you provided indicated issues with Class I medical devices manufactured by your firm. Additionally, you have no evidence of a complaint investigation of these complaints or justification for not conducting a customer complaint investigation.			
OBSERVATION 2 Top management did not provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by communicating to the organization the importance of meeting requirements, establishing the quality policy, ensuring the quality objectives are established and conducting management reviews.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Javonica F Penn, Investigator		DATE ISSUED 2/9/2026
X		Javonica F Penn Investigator Signed By: Javonica F. Penn -S Date Signed: 02-09-2026 11:14:02	

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Specifically, you have no evidence of establishing a quality policy, quality objectives, conducting management reviews, or providing quality system training to support the development and implementation of your quality management system.			
OBSERVATION 3 Processes needed for product realization were not planned and developed. Specifically, your firm manufacturers Class I, non-GMP exempt, medical devices, however you have not planned nor developed processes for risk management.			
OBSERVATION 4 Criteria for the evaluation and selection of suppliers were not established. Specifically, your firm manufactures Class I <i>Emergency Disposable Obstetrical</i> [medical device] <i>Kits</i>, but have no documented procedure for evaluation and selection of suppliers. Therefore, you have not completed evaluations of your suppliers to support the assurance of receiving quality components that meet your specifications.			
OBSERVATION 5 Purchasing information did not include a written agreement that the supplier notify your firm of changes in purchased product prior to implementation of any changes that affect the ability of purchased product to meet specified purchasing requirements. Specifically, you do not have evidence of written agreements with the suppliers of the Class I <i>Emergency Disposable Obstetrical</i> [medical device] <i>Kits</i> manufactured by your firm, to ensure you are receiving components that meet your specification and that you will be notified of changes that may			
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impact your devices prior to receipt. OBSERVATION 6 The inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements were not established and implemented. Specifically, your firm has not established documented procedures for incoming component inspection. Although your firm employee stated that your firm inspects incoming components for quantity, type, and visual integrity, these activities are not defined in a procedure, and the results are not documented. This applies to components used to manufacture your Class I, non-GMP exempt devices. OBSERVATION 7 Production controls do not include documentation of procedures and methods for the control of production, implementation of defined operations for labeling and packaging and implementation of product release, delivery, and post-delivery activities. Specifically, you have not documented the manufacturing, labeling, packaging, shipping procedures and work instructions used for the production of Class I, non-GMP exempt medical devices manufactured by your firm. *DATES OF INSPECTION 2/03/2026(Tue), 2/05/2026(Thu), 2/09/2026(Mon)			
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."