

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		DATE(S) OF INSPECTION 2/10/2026-2/12/2026 FEI NUMBER 3010882984			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jason I. Gumaer, Vice President Quality & Regulatory					
FIRM NAME Therapak Corporation		STREET ADDRESS 651 Wharton Dr			
CITY, STATE, ZIP CODE, COUNTRY Claremont, CA 91711-4819		TYPE ESTABLISHMENT INSPECTED Contract 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 Analysis of data indicating the quality management system is not suitable, adequate, or effective was not used as input for improvement. Specifically, your procedure SOP-QA016-01 Statistical Technique, dated 10/08/21, states you will use ANSI/ASQ Z1.4-2008 Sampling Procedures and Tables for Inspection By Attributes: General Inspection Level ^{(b) (4)}, (b) (4) for sampling (reduced) for your receiving inspection, in-process, and final inspection of medical devices. In review of your receiving acceptance of the primary component ((b) (4) (b) (4)) in device (b) (4), Manufacturer Part number (b) (4) (b) (4) for the past 2 years, I observed that your sampling was erroneous for all records I reviewed. Most of the quantities received for this material come in quantities of (b) (4) tubes each, and using the above sampling plan, it would require you to sample (b) (4) tubes, not (b) (4) as noted by your "Receiving Inspection Checklist." In addition, I reviewed your sampling for your manufacturing of the device (b) (4), Manufacturer Part number (b) (4) (b) (4) that you have been manufacturing since 2020. Your DHR (b) (4) an inspection sample size of ^{(b) (4)} each for lots of (b) (4) kits, which is the most common run					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Linda Galindo, Investigator </td> <td style="width: 40%; text-align: center; vertical-align: bottom;"> Linda Galindo Investigator Signed By: 2002546620 Date Signed: 02-12-2026 15:00:18 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Linda Galindo, Investigator	Linda Galindo Investigator Signed By: 2002546620 Date Signed: 02-12-2026 15:00:18 X
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size you manufacture. Using the statistical method in your procedure, the sample size should be (b) (4). You manufactured (b) (4) kits in 2025 that were under-sampled.			
OBSERVATION 2 Procedures for the feedback process have not been documented. Specifically, your procedure SOP-QA014-03 Complaint Handling and Nonconforming Events, dated 09-Feb-2026, states that complaints will be categorized for risk using factors of severity and frequency. In review of your complaint records for your material number (b) (4), Manufacturer Part number (b) (4) (b) (4) for the past 3 years, I observed that 8 of 8 complaints did not factor in risk or severity, yet a "low risk" designation was assigned for these complaints.			
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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."