DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	2/10/2026-2/13/2026
	FEI NUMBER 3005906810

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Karen E. Roberts, Officer Manager/Director of Operations

FIRM NAME	STREET ADDRESS
Automated Ophthalmics, Inc.	6671 Santa Barbara Rd Ste F
CITY, STATE, ZIP CODE, COUNTRY Elkridge, MD 21075-5842	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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

The medical device(s) label did not have a unique device identifier (UDI) present in.

Specifically, none of your labels included a UDI. Automated Ophthalmics, Inc manufactures Softips Plus Tip Covers which includes item numbers AO316: 100 Individually packaged sanitized tip covers for Tono-Pen and Accupen, AO200: 200 Individually packaged sanitized tip covers for Tono-Pen and Accupen, AO610: 600 Bulk Tip Covers, AO318: 300 Individually packaged sanitized tip covers for Tono-Pen and Accupen, and AO612: 600 Bulk Sleeved Tip Covers Sanitized.

OBSERVATION 2

Product was not protected from alteration, contamination, or damage during processing, storage, handling, and distribution by.

Specifically, your IFU and storage and handling requirements for the device entered by you in GUDID state that the product must be held at temperatures between 35 to 80 degrees Fahrenheit. You stated that if the product is held below 35 degrees Fahrenheit the latex can snap and when held above 80 degrees Fahrenheit that the latex can become discolored and brittle. You do not have procedures for and have not implemented monitoring of the temperature of the latex during shipping from the supplier, while the bulk latex supplies are held at the port, while the latex is stored in your warehouse awaiting manufacturing, while the finished product is stored in the shipping storage awaiting shipping, or during shipping to the customer of the finished product. Also, three of the four complaints received in the last 2 years were related to concerns from customers regarding heat damage to the finished product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christina D Mello, Investigator Andrea D Gomez, Investigator	X Christina D Mello Investigator Signed By: Christina D. Mello -S Date Signed: 02-13-2026 16:36:32	2/13/2026

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OBSERVATION 3
Complaint handling records were not adequately maintained.

Specifically, four of the four complaints received in the last two years did not have an investigation performed, the lack of investigation did not have a justification documented, there was no determination for the need to report the information to appropriate regulatory authorities, and there was no determination for the need to initiate corrections or a corrective action. For all four complaints the box "Improper use" was checked in the Conclusions section of the Complaint form. You stated this meant that you had determined that the customer was at fault but could not provide records of having performed an investigation to make this determination.

OBSERVATION 4
Nonconforming product was not adequately evaluated to determine the need for an investigation and notification of any external party responsible for the nonconformity.

Specifically, your SOP Non Conforming Product, SOP 37, Effective Date 09/19/22 states that the Quality Manager investigates, assesses scope and risk, maintains records, trends non conformances, and escalates recurring issues to CAPA. The SOP further states that scope determination includes identifying if the non conformance is isolated or lot-wide and that there is an evaluation for potential impact on safety, performance, sterility, integrity, intended use and compliance. Nonconformances must be trended; recurring or increasing issues trigger CAPA review, with trends assessed (b)(4). None of the nonconformance reports reviewed during this inspection for the last two years had a determination for a need for investigation or were evaluated for their scope, potential impact on safety, performance, sterility, integrity, intended use and compliance. You stated that in the last two years there has not been any trending of non conformities, no CAPAs initiated, or review of (b)(4) trends.

OBSERVATION 5
Records of complaint investigations do not include.

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Elkridge, MD 21075-5842	Manufacturer

Specifically, for four of the four complaints received in the last two years you did not record the UDI for the device.

X Andrea D Gomez
Investigator
Signed By: ANDREA D. GOMEZ -S
Date Signed: 02-13-2026 16:37:06

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Under consideration

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

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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."