February 23, 2026

Mr. Zayan
CEO
Daisy Instruments
Circular Road
Charag Din Plaza Sialkot
– 51310 - Pakistan

FEI: 3043181450

&

Mr. Mohammad Ashraf
Auditor
Quality Management Consultant
Khadim Ali Road,
Kotli Behram
Sialkot - Pakistan

Dear Mr. Zayan and Mr. Mohammad Ashraf:

This is to acknowledge receipt of the December 26, 2025, letter from Mr. Mohammad Ashraf (Auditor) certifying the compliance of Daisy Instruments (Establishment) with the United States Food and Drug Administration (FDA) Quality System Regulation of 1997, which includes the current good manufacturing practice (cGMP) requirements. The Quality System Regulation is set forth in Title 21, Code of Federal Regulations (CFR), Part 820.

The quality system audit report provided by the Auditor states that Daisy Instruments manufactures surgical instruments and that a quality system audit was performed on December 13, 2025. The inspection found deficiencies and the Auditor states that a corrective action plan was implemented on December 22, 2025. The Auditor recommends that the Establishment be added to the Green List of Import Alert 76-01, "Exempt from Detention Without Physical Examination of Medical Instruments from Pakistan."

FDA has reviewed the audit report of Daisy Instruments, including the Quality System Manual, Test Data, and the Corrective Action Plan submitted.

Based on our review, Daisy Instruments, will be placed on the Green List of Import Alert 76-01. The Establishment may begin exporting devices to the United States that were manufactured after the consultant certified the Establishment's compliance with the cGMP's; however, the Establishment's shipments are subject to the guidance outlined in the revised Import Alert 76-01.

The FDA may periodically detain and sample devices from the Establishment for verification of conformance to the Quality System Regulation. Failure of the sample will result in the Establishment being removed from the Green List of Import Alert 76-01 until the Establishment is re-inspected and documentation is submitted to the FDA to show compliance with the Quality

System Regulation.

The Establishment's placement on the Green List of Import Alert 76-01 is limited to medical instrument devices manufactured under the name of Daisy Instruments, Circular Road, Charag Din Plaza, Sialkot – 51310 - Pakistan. In the event the Establishment's name and/or manufacturing facility address change, FDA requests that notification be immediately forwarded to this office. A change in the name and/or address of the Establishment's manufacturing facility without notifying FDA will result in a re-evaluation of the compliance status of the Establishment.

The decision based on the Auditor's certification will remain in effect until such time that FDA is able to visit the Establishment for an inspection of the manufacturing facility. During this inspection all corrections and procedures will be evaluated and confirmed. Any new cGMP deviations, or any uncorrected deviations that were previously certified to, may result in a re-evaluation of the compliance status of the Establishment, including the possibility of removal from the Green List of Import Alert 76-01. You will be advised of the timing of FDA's inspection schedule.

If the Establishment has not conducted a Quality System audit in the past two years, we request that a Quality System audit be conducted within 6 months of receiving this letter. A copy of the Establishment's most recent audit should be submitted to FDA for review. The Establishment has a responsibility to conduct periodic Quality System audits to ensure conformance with the Quality System regulation.

The audit report should address, at a minimum, the applicable elements of the Quality System Regulation including the following information, as appropriate. This should not be considered an all-inclusive list and additional information may be included.

- Current Audit Summary
- Audit Follow-up Recommendations
- Corrective Action Plan
- Device Master Record
- Device History Record
- Material Analysis
- Material Hardness Tests
- Material Corrosion Tests
- Quality Manual
- Calibration
- Internal Audits
- External Audits
- Facilities
- Supplier Control
- Specifications
- Production Equipment
- Cleaning and Sanitation
- Personal Hygiene
- Training
- Hazardous Materials Handling
- Receiving, Storage, Shipping
- Traceability and Recall
- Consumer Complaints/MDRs
- Pest Control

All manufacturers exporting surgical instruments to the United States should use stainless steel meeting the latest version of the Standard Specification for Wrought Stainless Steels for Surgical Instruments, ASTM standard F-899. Please assure that the Establishment's documents and requirements conform to ASTM standard F-899.

Establishments that are involved in the production and distribution of medical devices intended for use in the United States are required to register and list the devices annually with the FDA. This registration and listing process may be completed electronically. For more information and to complete the process please go to: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm.

Electronic submission documents should be emailed to **cdrhocpakistanaudit@fda.hhs.gov**.

Cover letters contained in the electronic submission should be addressed to:

Ms. Deniz B. Mackey, Assistant Director
Imports and Registration & Listing Team
U.S. Food and Drug Administration - CDRH
Office of Regulatory Programs
Division of Regulatory Programs 2
White Oak Building 66
10903 New Hampshire Avenue
Silver Spring, Maryland 20993 USA

Please reference your Facility Establishment Number (FEI), 3043181450, in future correspondence and in the registration process.

If you have any questions regarding this correspondence, or need further assistance, please contact Edward Nyack at Edward.Nyack@fda.hhs.gov or (240) 402-4400.

Patrick Bowen
Team Lead
Imports and Registration & Listing Team
Division of Regulatory Programs 2
Office of Regulatory Programs
Center for Devices and Radiological Health