



LL-C
Certification

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SURVEILLANCE AUDIT REPORT NO. 920117
ISO 13485:2016

written on Saturday, 18 January 2025

in the company

FACT-N-FAIR INDUSTRIES



CUSTOMER GENERAL DATA

FACT-N-FAIR INDUSTRIES

P.O Box # 1771 Building # 8, Small Industrial Estate, Shahab Pura
51310 Sialkot
Pakistan
Reg. No. 3643781 PK

Contact person

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The main scope of the company for which certification management system is considered

Manufacturing & Export of Surgical and Dental Instruments

Corresponding technical area	1 (ISO 13485)
Number of employees in the certified area	3
Number of filials outside of the registered seat	0
Special processes	
The certified processes are ensured	by own employees without exception
Design and development applied	NO
Number of Shifts	1.00

CERTIFICATION DATA PROCESS

Certification standard applied	ISO 13485:2016
Audit date	01/18/2025 08:00:00 - 01/18/2025 14:30:00
Certificated since	01/10/2023
Place(s) of Audit	headquarters
Audit Coordinator and Lead Auditor	Sarwar Anjum (ISO 13485:2016)
Other participants of the audit (and their position)	Anjum Sarwar, Ail Sheikh, Hamid Ali
Audit Plan Date	Monday, 13 January 2025
Total Audit Days (on the spot)	0.99 (0.79)
Deviation from the audit plan	NO
Significant issues impacting on audit programme or client's MS	NO
Consultant involved in management system support	No
Audit (Report) language	English

1. AUDIT SCOPE

Audit Criteria

The audit criteria are the requirements of the standard and the established processes as well as the documentation of the organization's management system. The purpose of the audit is to confirm the compliance of the client's management system with the audit criteria, to determine the ability of the management system to ensure that the organization meets the relevant legal and other requirements (but the audit is not an audit of compliance with the legislation). Furthermore, the objective is to determine whether the effectiveness of the management system makes it possible to achieve the objectives set and identify areas for potential improvement.

Description of the audited company and its activities

Corporation details, infrastructure, working places and branch offices, organizational chart description

P.O Box # 1771 Building # 8, Small Industrial Estate, Shahab Pura
51310 Sialkot

Manufacturing equipment or services support activities

Fabricate precision components.
Assemble machinery.
Test for reliability.
Provide ongoing maintenance and support for seamless surgical instrument manufacturer.

Description of the main product or services

The Main product of FACT-N-FAIR INDUSTRIES is Surgical and Dental Instruments.

Human resources

HR processes for employing and empowering human resources
Identifying roles & responsibilities Providing opportunities for attaining competencies, Assessing the effectiveness of training
Planning, reporting and retaining associated.

Scope of certification

Manufacturing & Export of Surgical and Dental Instruments

Areas excluded from certification

Design & Development , Installation activities, Servicing activities, sterilization, Customer property; Preservation of product are excluded from certification.

Audit Objectives

Audit objectives, where methodologically can 1) confirm the compliance of the client's management system with audit criteria, 2) determine the ability of the management system to ensure that the organization meets the applicable statutory, regulatory and contractual requirements, and 3) achieve the specified objectives, as the management system can identify areas for potential improvement, including management review and internal audits - Were fulfilled.

Certification procedure

Disclaimer

Auditing is based on a sampling process of the available information and consequently there will always be an element of uncertainty present in auditing evidence, which may be reflected in the audit findings. Those relying or acting upon the audit results and conclusions should take into account this uncertainty.

Opening and closing meeting participants

Anjum Sarwar, Ail Sheikh, Hamid Ali

Audit methods

A remote CAAT / ICT assessment was performed to the extent 10 % Form of audit: video conferencing (VIBER®, SKYPE®, etc.), email communication

Volume of sales, products, orders, services, as applicable

In the fiscal year 2024, the company's surgical division reported a sales volume of 06 lac, marking a 8% increase compared to the previous year.

Description of sampling and sampling statistics

Samples were collected randomly at site and evidence was collected based on interview with staff and technical persons

Significant changes impacting the MS of the organization occurred since the previous audit and unresolved issues

No significant changes have occurred in the organization management system, no previous audit

LOGO of the Certification Body and certification reference

is used by common way and is not misleading and is not inconsistent with business conditions

2. SYSTEM DESCRIPTION AND COMPLIANCE MATRIX - ISO 13485:2016

System description

Quality manual; Control of internal and external documentation; Control of records

checked the quality manual and system documentation and control of records (FNF-QM-001/00). FACT-N-FAIR INDUSTRIES and top management is committed to the implementation of ISO13485 QMS. Instructions were available at the facility related to work and safety. All details processes are mentioned in QMS.CEO is well aware of importance of QMS. Requirements of interested parties are identified in QMS, considering interested parties as statutory bodies, customers, vendors, employees which are required for conformity of company process.

QMS processes - identification, determination of criteria and methods, planning, changes control

FACT-N-FAIR INDUSTRIES management has applied MD QMS in all the departments of organization. Documents of ISO 13485 are maintained as per Certification scope. Management of CD ensures that ISO 13485. Standard is applicable to all processes within all the departments of the organization.

Responsibility; Authority; Management commitment and representative; Internal and external communication

ISO 13485 Quality Manual QMS, roles, responsibility & authorities defined & communicated within company. Job descriptions for all positions are defined. checked the Job Description of QA manager (FNFJD-QAM-001/00). Recruitment of employee is done by HR Manager as per pre-defined job descriptions. I have interviewed purchase manager, HR manager and they are aware of their responsibilities. Requirements & importance QMS is communicated by Top management through documents and emails within the company & with clients.

Applicable regulatory requirements; Medical device file; Role(s) under the applicable regulatory requirements

FACT-N-FAIR INDUSTRIES is a legal manufactures products like surgical and dental Instruments. I Checked the Applicable regulatory requirements refer to the specific rules, laws, and guidelines set by governing bodies. Device File: A comprehensive record detailing the device's description, quality management, risk management, and post market surveillance. Roles: Quality Assurance Manager ensures regulatory compliance, Regulatory Affairs Specialist handles submissions and updates, and Post Market Surveillance.

Quality policy and objectives; Risk analysis of processes

ISO 13485 standard implementation, Customer satisfaction, Good Quality Products and on time delivery is FACT-N-FAIR INDUSTRIES top priority as its Quality policy. Quality policy (FNF-QP-001/00) is documented, pasted on all departments whiteboards and and verbally communicated to the employees. Objectives include continual improvement, staff training, and adherence to industry best practices. Surgical Company's quality policy prioritizes patient safety and product excellence, with objectives focused on continuous improvement and regulatory compliance. Sighted Risk Analysis SOP document (FNF-RA-02/00) dated 22 April 2024, Risk analysis of processes involves identifying, assessing, and mitigating potential hazards across manufacturing, distribution, and clinical use.

Management review; Internal audits

Checked all documentation of Management Review SOP (FNFMR-01/00), minutes of meeting (FNFMRM-01/00), was conducted on 18th October 2024 chaired by CEO, Management reviews in CD involve top -level assessments of quality performance, regulatory compliance, and strategic objectives alignment. Regular evaluations by senior management to assess the quality management system's effectiveness and compliance with regulatory requirements. Internal Audits: Systematic, independent examinations of the quality management system and processes to ensure conformity with internal and external standards. QAM Mr. Kamal had conduct internal audit(FNFIA-01/00) on 22 Aug 2024, Internal audits, conducted at scheduled dates, evaluate compliance with standards and regulations, informing improvement initiatives.

Resources management; Human resources - competence, training, awareness

CEO has recruited the HR Manager. HR manager reviews the requirement of resources & also update the management of resources activity. Job descriptions for all positions are defined. Recruitment of employee is done as per pre-defined job descriptions. On Job trainings are conducted to enhance the personnel knowledge about QMS importance. Verified. Training records are maintained by HR manager (FNFHR-001), training program (FNFTP-001), training record (FNFTTR-001), record of attendance (FNFRTA-001) CEO is committed on conducting meetings for improvement.

Work environment; Infrastructure - facility, services, software, maintenance; Monitoring and measuring equipment

FACT-N-FAIR INDUSTRIES is following Pakistan Municipality rules for disposal of waste. Also use of restricted chemicals is prohibited at the facility like chromate 5 etc. Acids are disposed as per environmental safety standards. Plastic material is disposed with the help of municipality. Use of facemasks & sanitizer is must at organization. Work environment is found to be effective Adequate lighting, adequate space, ventilation, temperature, & humidity are maintained.

Product related requirements and Customer focus - planning of product realization, documented requirements, communication

Checked production facility and products being manufactured as per planned customer requirements and MDQMS as per Customer purchase order. Production Manager is determining and reviewing requests for products and communication with customers according to sales procedure and procedure for customer communication respectively documented in (FNFSP-01/00) (FNFCC-01/00).

Design and development

Design and development are not applicable.

2. SYSTEM DESCRIPTION AND COMPLIANCE MATRIX - ISO 13485:2016

continuation ...

Purchasing - information, monitoring, evaluation and auditing of suppliers; Outsourcing control

Purchasing is done from approved suppliers for Brass, Plastic etc. & POs with Bills are maintained. Suppliers are selected by criteria defined in Supplier Selection Form. Outsourcing activity is controlled by purchase manager. In-coming inspection is done by QC person & records are maintained. After clearance from QC, products are added in inventory.

Product realization - production control, services provision

In product realization, FACT-N-FAIR INDUSTRIES implement stringent production control measures to ensure consistency and quality across all surgical device manufacturing processes. Additionally, FACT-N-FAIR INDUSTRIES services provision entails comprehensive customer support, training, and maintenance, ensuring seamless integration and optimal utilization of our products within healthcare settings.

Validation of processes and software; Identification and traceability

FACT-N-FAIR INDUSTRIES validation of processes and software involves confirming their compliance with standards and specifications, ensuring their reliability, effectiveness, and regulatory adherence for consistent performance. FACT-N-FAIR INDUSTRIES has its traceability plan as per, batch no. and lot no. Validation are preformed by properly. Traceability is maintained at all operations from raw material inward to dispatch of material. Raw material after QC check, kept in Inward OK area with tags having PO no. Product is identified with Batch no. & Mfg. date Verified In process stage inspection report for QC person, qty checked, parameters and specifications are found ok.

Contamination control, Cleanrooms, Sterilization process

FACT FAIR is following Pakistan Municipality rules for disposal of waste. Also use of restricted chemicals is prohibited at the facility like chromate 5 etc. Acids are disposed as per environmental safety standards. Plastic material is disposed with the help of municipality. Use of facemasks & sanitizer is must at organization. Work environment is found to be effective Adequate lighting,adequate space, ventilation, temperature, & humidity are maintained. Sterilization is excluded from scope of work.

Installation activities; Servicing activities; Customer property; Preservation of product

Installation activities; Servicing activities; Customer property; Preservation of product are excluded for ISO 13485

Actions to nonconforming product before and after delivery; Rework

Checked Procedure for Corrective & Preventive Action (FNF-CPA-01/00), along with CPAR request and registry for CPAR. Checked procedure for non conforming products (FNF-NCP-01/00) and NCP record, NCP register and NCP recall documents. CEO & QC are closely monitoring all the processes. If after delivery any issue or NCR is raised by customer then it is addressed by product recall plan. Corrective actions are performed. For customer satisfaction, replacement of products can also be taken into considerations.

Feedback; Complaints handling; Vigilance and reporting to regulatory authorities

FACT-N-FAIR INDUSTRIES IS meeting all its customer needs. Verified Customer Feedback given was satisfactory. Root cause have been identified with corrective action & verified by CEO and QA. Customer Complaints are resolved & recorded in Customer Complaint Register. Verified procedure for handling complaints. Verified the procedure for Product recall & Advisory notices.

Measurement, analysis and improvement; Corrective and Preventive actions; Monitoring of product and processes

Measurement, Analysis, and Improvement ISO 13485 emphasizes using data driven methods to assess and enhance process and QMS. The standard requires systematic approaches to address nonconformities corrective action & prevent their recurrence preventive actions. These actions are crucial for maintaining compliance, improving processes, and preventing issues. ISO 13485 stresses the need to monitor both the products being manufactured & the processes used to make them.

Compliance matrix - ISO 13485:2016

Standard element	Fulfillment degree	Next audit verification
General requirements, process control, role(s) under the applicable regulatory requirements (4.1)		YES
Quality manual, documentation control and related requirements, Medical device file (4.2)		YES
Quality policy and objectives; Management commitment (5.3, 5.4.1, 5.1)		YES
Responsibility, authority and communication (5.5, 7.2.3)		YES
Management review (5.6)		YES
Planning of management system and product realization (5.4, 7.1)		YES
Resources management (6.1, 6.2)		YES
Infrastructure; Control of monitoring and measuring equipment (6.3, 7.6)		YES
Working environment, contamination control (6.4)		YES
Design and development (7.3)		NO
Purchasing and purchased product verification, supplier evaluation, outsourcing (7.4)		YES
Requirements related to the product; Customer focus (7.2.1, 7.2.2, 5.2)		YES
Control of production and services provision, cleanliness of the product, installation and service activities (7.5.1-4)		YES
Validation of processes for production and services provision, sterilization (7.5.5-7)		YES
Identification and traceability (7.5.8, 7.5.9)		YES
Customer property; Preservation of product (7.5.10, 7.5.11)		YES
Feedback, Complaints handling, Vigilance and reporting to regulatory authorities (8.2.1-3)		YES
Actions to nonconforming product before and after delivery, rework (8.3.1-4)		YES
Measurement and analysis of the data (8.1, 8.2.5, 8.2.6, 8.4)		YES
Internal audits, Improvement, Corrective and Preventive actions (8.2.4, 8.5)		YES

	Standard requirements and own management dossier are properly met. Outstanding deficiencies are recognised and removed during the process
	Standard requirements and own management dossier are properly met. Outstanding deficiencies are not always recognised/removed during the process; or fall under disclosure requirements of standard with no benefit for a company. Auditor can make exceptions
	Standard requirements and own management dossier are not properly met. Auditor opts for exception or non-conformity according to the extent and its impact on system functionality

3. AUDIT OUTCOME SUMMARY

3.1. Strengths of the company

ISO 13485:2016

FACT-N-FAIR INDUSTRIES is committed for maintaining Good Quality Products, On time deliveries Customer Satisfaction. CEO & Managers were aware of the system implementation. Each work is recorded as per QMSMD.

3.2. Nonconformities and Areas of improvement

Summary of nonconformities and areas of improvements

No nonconformity or area of improvement

3.4. Previous audit (2024)

Audit type	Surveillance audit
Aannounced / Unannounced	Announced
Audit date	02/22/2024 08:00:00 - 02/22/2024 14:30:00
Name of auditing organization	LL-C (Certification) Czech Republic a.s.
Coordinating auditor	Anjum Sarwar
Action taken on NCs raised at previous audit	Please, refer to section 3.3 "Findings from the previous audit and verification of effective implementation of corrective actions."

Details about the current certificate and certification cycle

Standard name	ISO 13485:2016
Certificate number	920117
Certificate validity code	67E8911A-1A9
Certificate expiry date	01/09/2026



4. CONSECUTIVE ACTION, FINAL PROVISIONS AND RECOMMENDATION

Thanks to all who participated in the organization and also to those who took part in the audit. We are glad that the management system audit in your company runs smoothly and in a friendly atmosphere.

Expected Outcomes

Applicant for certification (certified company) has been informed about the suitability of the accredited certification in the sense, that: "for the defined certification scope, an organization with a certified management system, which meets and appropriately applies the applicable management system requirements, can ensure the permanent provision of its service or/and its products satisfying customer requirements, relevant laws and regulations in order to increase customer satisfaction".

Use of the LL-C logo

Upon obtaining a valid certificate, the client is entitled, for the duration of the certificate validity, to use an approved logo of the certification company or a private scheme. In case of system certification, process certification or technical documentation completeness assessment, this mark shall not be used on a product or product packaging seen by the consumer or in any other way that may be interpreted as denoting conformity of a specific product. The use and placement of the logo must not create confusion between the client and the certifying company, or convey a false impression that the certification applies to a specific product instead of the management system, unless it is clear from the certification scheme that it is not about assessment of a specific product, where its compliance with essential requirements is verified, which are given by a normative or other legal document.

Settlement of nonconformities, areas for improvement

The findings of the audit are given in a previous chapter, in the form of nonconformities and Areas for improvements. We kindly ask you to settle them as follows:

Major nonconformity

If it has been found, it shall be formulated in the Nonconformity Protocol, which is annexed to this report. Major Nonconformity is such insufficient fulfilment of the standard requirements that the certificate cannot be issued (or must be commenced its removal) unless is finished its settlement by the applicant for certification. When a major nonconformity is issued during an audit, the client must provide the CB with objective evidence of an investigation into causal factors and the risks they expose and their proposed corrective action plan (CAP). This shall be provided within 30 days after the audit. Settlement procedure must be formulated by the applicant on the same form (Nonconformity Protocol). The major nonconformity shall be closed within a further 30 days by implementing a corrective action (CA) and submitting evidence to the CB. When a satisfactory settlement of nonconformity is finished, audit can be completed with positive results. The CB provides the method of verifying of the nonconformity settlement.

Minor nonconformity

The Minor nonconformity is such insufficient fulfilment of the standard requirements that the certificate can be issued without finishing Minor Nonconformity settlement by the applicant. A root analysis and a proposed corrective action plan is required within 30 days after the audit. Certification body must be informed about the settlement or about the objection on its relevance within 12 months from the last day of the audit or during the next audit. The method for verifying the settlement of this minor nonconformity is subject to surveillance or recertification audit. In the case of insufficient settlement of the minor nonconformity, it should be reclassified as major nonconformity and threaten the validity of the certificate.

Area for improvement

The area for improvement is a comment for improving of the management system or the better and efficient fulfilment of standard certain requirements (notably the removal of formal fulfillment of the standard requirements of or optimization solutions) . According to the accreditation criteria the certified company need not respond actively to these findings, but when there are lots of areas for improvement and will be ignored, it can be considered during the subsequent audit as a reduced level of system performance.

Certification period and certificate validity

The period, for which certified company is committed to maintain a functional management system and certification body is committed to provide the surveillance audits, corresponds to the certificate validity. During its validity, the certification body is obliged to perform surveillance audits every year in the place of the certified company activities, unless a normative or legal requirement exceptionally states otherwise. The first surveillance audit after initial certification shall be commenced within 12 months from the date of the completion of the certification audit; the second surveillance audit must be initiated in the annual period from the date of completion of the first surveillance audit with a maximum tolerance of 45 calendar days.

Before the termination of the certificate validity a contract with possible price advantage will be offered for the next certification period, if the client is interested in it (while the scope of certification will remain). To keep the price advantage, the recertification audit/ assessment shall be carried before the expiration of the original certificate. In severe cases, it is possible to request a postponement of surveillance audit, the approval of this exemption is solely on the certification body. In case of failure to cooperate in a surveillance audit we must begin the process of withdrawing of the certificate and we must publish that fact, according to the accreditation criteria.

Obligations of the certified company

The basic duties of certified company arise from the contract and business conditions that are part of it.

The certificate holder shall maintain its management system functional throughout the certificate validity period and apply all changes in the management systems that result from the changes in the relevant standards requirements or accreditation criteria based on the recommendations sent by the certification body

Further the certified company is obliged to register and document all complaints by third parties relating to its management system and properly inform the certification body.

Obligation of the CB / NB 2435

The basic duties of certification body arise from the contract and business conditions that are part of it. Certification body shall maintain its accreditation status, conduct regular audits and surveillances according to the specified dates and time frames and provide objectivity in determining the operability of the management system. Further the certification body is obliged monitor changes in the requirements of the relevant standards and notifies the certified company accordingly in advance and process complaints and reservations raised by the client or a third party in a timely manner.

Appeal

Applicant for certification (certified company) is entitled to lodge any complaint against procedure of the certification body or individual auditors. Complaint of the applicant for certification (certified company) is to be sent in writing. Likewise applicant for certification (certified company) can comment this report. Severe appeal, as the claim against auditor impartiality or the decision of the certification company to refuse issuing or withdrawal of the certificate, are solved by the independent Appeal Committee within the period 30 days. Other comments and objections are dealt with operationally in an appropriate period of time.

Report provision to third parties

This report summarizes the results of the audit. The report is provided to the customer, one copy in electronic format is deposited with the LL-C (Certification). The customer is entitled to present to any third party the full report only. The contents of this report and all audit records are considered confidential. The contents of this report and all audit records are considered confidential. The reports may be presented to any third party only with the consent of the customer, without that authorization if the accreditation body and the owners of private schemes will request it.

Recommendation

The overall audit target (as specified in the plan) was achieved. The documented system management conformity was measured through highly qualified process. Further, client's activity was compared with standard requirements. It was confirmed that the organization's MS is capable to meet the applicable requirements of the relevant standard(s) and achieve the expected outcomes for accredited Certification as stated in ISO-IAF Communiqué for Accredited Certification. The organization meets and appropriately implements the applicable MS requirements, and can ensure the continued provision of this service or products in conformity to customer requirements and relevant laws and regulations in order to increase customer satisfaction. This statement was made on the assessment of the individual standard's requirements fulfilment level, as evidenced in the compliance matrix of this report. The audit objectives as specified in Section 1 - Audit Scope were successfully met. Furthermore, the scope of certification has been assessed to be fully representative of the current activities of the audited organization.

I recommend, taking into account the audit results:

to maintain management system certificate with the requirements of the standard ISO 13485:2016

for the scope

Manufacturing & Export of Surgical and Dental Instruments



LL-C (Certification) Anjum Sarwar

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