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ANAB
ANSI National Accreditation Board
ACCREDITED
ISO/IEC 17021-1
MANAGEMENT SYSTEMS
CERTIFICATION BODY

American Systems Registrar, LLC, a provider of third-party system registration and accredited by the ANSI National Accreditation Board attests that:

STRAITEK, LLC

26 COMMERCE DRIVE
DANBURY, CT 06810

with a scope of:

CNC MACHINED PARTS & INJECTION MOLDED PARTS

has established a quality management system that is in conformance with the International Quality System Standard

ISO 13485:2016

ASR Certificate Number:	**7218**
Date of Certification:	**July 23, 2024**
Date of Certification Expiration:	**July 22, 2027**
Date of Initial Registration:	**July 25, 2018**
Revision:	
Re-Issue Date:	

President

CERTIFICATE OF REGISTRATION

StraiTek
Business Management System Manual

Doc. # BMS-1
Rev. 7
Date: June 14th, 2021

REVISION & AMENDMENT RECORDS

Revision	Date	Description	Approved by
1	3/14/2013	Initial Release	BS
2	5/1/2016	Updated to ISO 9001:2015	BS
3	8/31/2016	Minor spelling corrections	BS
4	4/15/2018	Revised to ISO 13485:2016 requirements	BS
5	7/1/2018	Added Section P7.6-2 (CNC Software Validation)	BS
6	1/7/2019	Registered with FDA	BS
7	6/14/2021	Removed FDA Registration	BS

INTRODUCTION

Straitek has developed and implemented a business management system to demonstrate its ability to consistently provide products that meet customer and applicable regulatory requirements and to address customer satisfaction through the effective application of the system, including continual improvement and the prevention of nonconformities.

The Business Management system complies with the International Standard ISO9001 & ISO 13485

SCOPE:

The Quality System documentation is written and implemented to meet the requirements of ISO 13485 with a scope of registration for: **Manufacture of CNC Parts** and: **Molded Components for Medical Device Applications.**

The purpose of this manual and the associated procedures is to describe the Quality Management processes and the relationship between those processes that collectively control operations at the StraiTek facility. The numbering in this manual reflects the structure of the ISO 13485 numbering system.

Not Applicable ISO 13485 Requirements:

Section 7.2.1 (a) & 7.5.1 (f), post-delivery activities, 7.5.1 Control of Production and Services Provision – Exclude Services only. StraiTek is not responsible for after sales services. Section 7.5.6, Validation of processes for production and service provision is also excluded. All the part features fabricated at StraiTek are monitored and measured after the molding process.

Section 7.3 Design and Development StraTek does not have does not have design responsibility. StraTek creates molds to fabricate components to their customers design requirements.

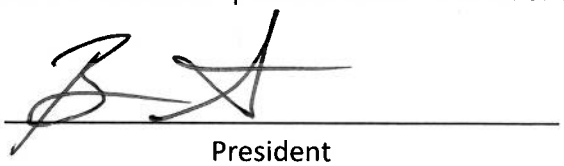
Sub clauses in section 7.0 pertaining specifically to medical device manufacturers such as: 7.5.3, 7.5.4, 7.5.5, 7.5.6.7.5.7, & 7.5.9.2.

This manual is formally reviewed as part of the annual Management Review Meeting to ensure that any changes in the Quality System are documented.

PURPOSE:

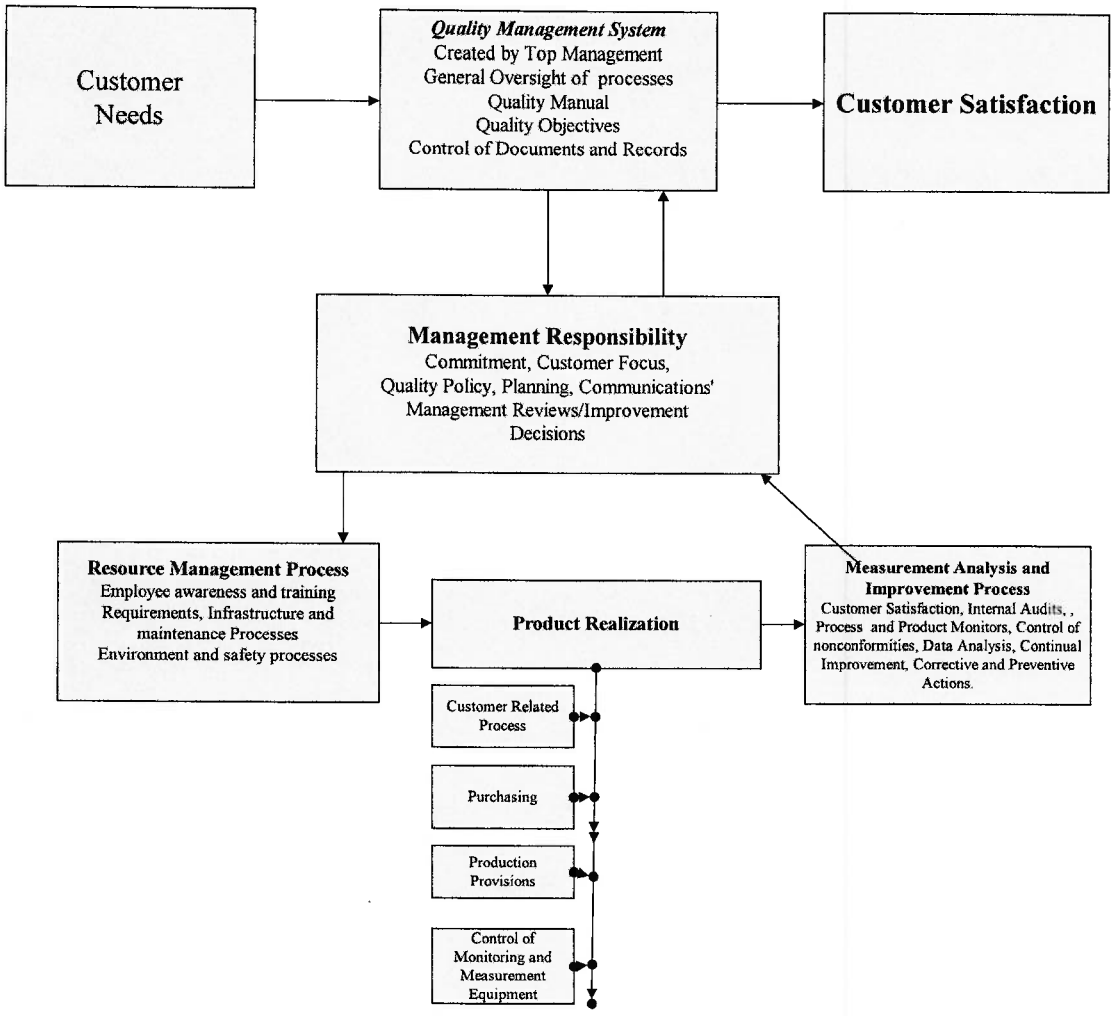
The purpose of this manual is to define and describe the business management system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide general procedures for all activities comprising the quality system.

Another purpose of this manual is to present the business management system to our customers as well as other external interested parties to inform them of what specific controls are implemented at StraiTek



President

Interaction of Processes



Quality Policy StraiTek

StraiTek is committed to:

- **Producing quality products**
- **On-time delivery**
- **Continuous improvement of the QMS processes.**

We provide the Highest Quality by:

- Consistently meeting our customer's expectations for product quality and performance.
- Timely delivering our products and services to meet our customer's requirements.
- Ensuring our personnel are properly trained so they are better able to serve our customers.
- Encouraging employee involvement in product improvement.
- Timely reviewing all internal and external procedures for enhancement of customer service and satisfaction.

Mission Statement:

StraiTek strives to be our customers' 1st choice for CNC prototypes and molded products by consistently achieving quality products, on time delivery, and services for our customers.

Measurable Key Performance Indicators:

1. Quality products to customers.
2. Delivery performance to customers.
3. Supplier performance – quality & on-time delivery.
4. Quote win rate.

The Quality Objectives are reviewed at each Management Review Meeting. The Objectives are posted on the bulletin board for employees.

Brian Straiton

ISO 13485:2016 Section	Procedure, Work Instruction #	Description	Form #	Description
Section 4, Quality Management System				
4.2.2 Quality Manual	BMS-1			
4.2.4 Control of Documents	P 4.2.4-1	Control of Documents		
4.2.5 Control of Records	P 4.2.5-1	Control of records		
5 Management Responsibility				
	P 5.6-1	Management Responsibility	F 5.6-1	Management Review Minutes
6 Resource Management				
6.2 Human Resources	P 6.2.2-1		F 6.2.2-1	Training Log
			F 6.2.2-2	Competency Assessment
6.3 Infrastructure & Preventive Maintenance	P 6.3-1		F 6.3-1	Infrastructure
			None	Machine Maintenance Logs
7 Product Realization				
7.1 Planning of product realization			F 8.2.6-1	CNC Control Plan
			F 8.2.6-2	Molding Control Plan
7.2 Customer Related Process	P 7.2-1	Customer Related Process	F 7.2-1	Risk Mitigation
7.4 Purchasing	P 7.4-1	Purchasing	F 7.4-1	ASL
			F 7.4-2	Purchase Order
			F 7.4-3	Key Supplier Self Evaluation
			F 7.4-4	Supplier Evaluation (Short Form)
			F 7.4-5	Supplier Performance
7.5 Production Provisions	P 7.5-1	Production Provisions	F 8.2.6-1	CNC Control Plan

			F 8.2.6-2	Molding Control Plan
7.5.2 Preservation of product	P 7.5-2	Shipping, Receiving & Inventory Control		
7.6, Control of Monitoring and Measurement Equipment	P 7.6-1	Control of Monitoring and Measurement Equipment	F 7.6-1	Calibration Log
	P 7.6-2	CNC Software Validation	F 7.6-2	CNC Software Validation
8 Measurement Analysis & Improvement				
8.2.1, Feedback	P 8.2.1	Feedback	F 8.2-1	Customer Satisfaction Survey
8.2.2, Complaint handling	P 8.3-1	Control of Nonconforming Product		
8.2.3 Reporting to regulatory authorities	P 8.5.2-1	Corrective action		
8.2.4 Internal Audit	P 8.2.5-1	Internal audit	F 8.2.4-1	Audit Schedule
			F 8.2.4-2	Audit Report
8.2.6-1, Monitoring and Measurement of Product			F 8.2.6-1	CNC Control Plan
			F 8.2.6-2	Molding Control Plan
			F 8.2.6-3	FAI
			F 8.2.6-4	Capability Study
8.3, Control of Nonconforming Product	P 8.3-1	Control of Nonconforming product	F 8.3-1	NMR Log
			F 8.3-2	Nonconformance Report
			F 8.3-3	RMA Log
8.5.2-1, Corrective Action	P 8.5.2-1	Corrective action	F 8.5.2-1	CAR Log
			F 8.5.2-2	CAR Report
			F 8.5.2-3	Customer Complaint Log
8.5.3, Preventive action	P 8.5.3-1	Preventive Action / Continuous Improvement	F 8.5.3-1	PA/CI Log