Automation Tooling Systems Inc.

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1.0 ATS GLOBAL QUALITY POLICY

ATS is committed to 100% total customer satisfaction and compliance with regulatory requirements.

Every ATS employee is committed to meet Customer Requirements (Cost, Schedule and Quality).

By continuously improving the operation, we will contribute to the success of our customers, employees, suppliers and stakeholders. ***(applicable to 9001 divisions only)***

By continuously improving our processes and maintaining the effectiveness of the quality system, we will contribute to the success of our customers, employees, suppliers, and stakeholders. ***(applicable to 13485 divisions only)***

2.0 THE ATS VISION

Delivery excellence in innovative manufacturing solutions to the world's most successful companies.

3.0 THE ATS MISSION

We will achieve our Vision by providing:

- Outstanding value to our Customers globally.
- Superior financial return to our Shareholders.
- A premier work environment and career opportunities for Employees.

We will accomplish our Mission by:

- Differentiating ourselves by providing outstanding value through the practical and innovative application of state of the art technologies.
- Maintaining focus on our core business of providing automated manufacturing solutions to companies in diverse industries.
- Developing long term relationships with key customers.
- Enhancing our ability to serve key customers by utilizing our technological strengths to manufacture high Quality component parts and assemblies, and provide related services.
- Creating a distinct, high-performance workplace where all employees build success for their customers and for their careers.

4.0 CORE VALUES

We believe that observance of the following **values** is fundamental to the success of our business. These **values** will be reflected in our long-term objectives as well as our current year objectives:

Customer Focused
Our future depends on our contributions to our customers' success. We will exceed our customers' expectations, deliver on our commitments, and treat our customers with professionalism, courtesy and respect.

Profitability is Essential
Long term viability of ATS can only be achieved if adequate profits are generated on a regular basis to make investments for the future in employee training, product development and facilities. This will provide our customers, employees, suppliers and shareholders with security and stability.

A Dedication to High Quality
This must be inherent in all aspects of our operations, products, and services, and reflected in the way we function as an operation. Every employee is responsible for meeting or exceeding the expectations of those who depend upon him/her.

Fostering Innovation Through Controlled Risk
We must continue the entrepreneurial spirit and innovative use of technology that made ATS a leader in its markets. Risk taking will be controlled and undertaken with the understanding that not all innovations are successful.

Continuous Improvement
We believe that in all aspects of our business it is essential to continuously raise the standards of acceptance and efficiency. The search for excellence must never stop.

Human Resources Are Our Most Valuable Asset
Our foremost competitive edge is the Quality of our people. We will promote a sense of teamwork and unity through effective two-way communication, showing respect for the individual along with just and fair management practices.

Be A Good Corporate Citizen
We will be a good corporate citizen. We will take pride in the appearance of our properties, show respect for the environment, and conduct our business in a socially responsible manner. We will join with our employees in supporting the communities where we are located.

Ethical Business Practices Will Not Be Compromised
We will apply the "Golden Rule" and treat others as we wish to be treated. This applies to relationships with customers, suppliers as well as our fellow employees.

5.0 ORGANIZATION AND AUTHORITY FOR QUALITY

The ultimate authority within the ATS management structure shall be the CEO. The Senior VP of ASG North America assigns the responsibility for managing the Global Quality System to the Global Director of Quality and is appointed as the Global Quality Management Representative. These responsibilities include:

- The task of ensuring actions have been taken to achieve planned results and overall maintainance to ensure on going effectiveness of the Global QMS
- The promotion of awareness of customer requirements throughout the organization and for liaison with external parties on matters relating to the business management system.

6.0 QUALITY MANAGEMENT SYSTEM SCOPE

The organization's business management system conforms to ISO 9001:2008. The global Quality Management system scope is:

Region	Site Information	
CANADA	Building 1 730 Fountain Street North Cambridge, ON. N3H 4R7	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
CANADA	Building 3 730 Fountain Street North Cambridge, ON. N3H 4R7	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
CANADA	600 Chrislea Road Woodbridge, ON. L4L 8K9	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
CANADA	Building 2 730 Fountain Street North Cambridge, ON. N3H 4R7	Manufacture, commission, and service of photovoltaic modules, computerized instrumentation, functional testing, and turnkey automation systems and equipment
USA	1510 Cedar Line Drive Rock Hill, SC 29730	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
USA	2121 NE Jack London Street Corvallis, OR 97330	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
USA	425 Enterprise Drive Lewis Center, OH 43035	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment

USA	ATW - 12847 Stark Rd. Livonia, Michigan 48150	Design, manufacture and integration of test and fluid production/development systems for the diesel, automotive, recreation and other industries. Design and building trst equipment-management, design, program management quality, manufacuture/assembly and support systems.
USA	ATW – 313 Mound Street Dayton, Ohio 45407	Design and manufacture of assembly and test systems for the automotive, appliance electronic and pharmaceutical industries.
USA	Sortimat – 5655 Meadowbrook Industrial Court Rolling Meadows, IL 60008	The design, manufacture and service of automated assembly machinery
SWITZERLAND	Grosszelgstrasse 21 Würenlos Switzerland, CH-5436	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
GERMANY	Marsstrasse 2 D-85551 Heimstetten	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
GERMANY	Sortimat - Birkenstrasse 1 - 7 71364 Winnenden Germany	The design, production, sales and service of feeder technology
GERMANY	Sortimat - Birkenstrasse 1 - 7 71364 Winnenden Germany	The design, production, sales and service of assembly technology
GERMANY	Heinkelstrasse 10 78056 Villingen-Schwenningen Germany	Design, production and service of handling technologies
GERMANY	ATW - Carl-Borgward Strasse 11 56566 Neuwied Neuwied, Germany	Design, manufacture, installation, commissioning, and service of assembly and test equipment, including associated software development. *THIS SITE IS NOT CONTROLLED UNDER THE GLOBAL CERTIFICATION*
SINGAPORE	38 Jalan Peminpin, #01-01 Wisdom Industrial Building Singapore 577178	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
MALAYSIA	Plot 221, Lorong Perindustrian Bukit Minyak 11, Mukim 13, Kawasan Perindustrian Bukit Minyak, 14000 Bukit Mertajam, Seberang Perai Tengah, Penang, Malaysia	The manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
CHINA	153 Huang Hai Road TEDA Tianjin People's Republic of China 300457	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment

INDIA	Sortimat - 191/A1, Station Road Chinchwad, Pune-411 033 India	Design, Manufacture, Supply and Servicing of Machines for Assembly Technology & Feeding Technology Solutions

The organization's business management system conforms to ISO 13485:2003 as applicable to specific divisions. The Quality Management system scope is for these divisions is as follows:

CANADA	APG Building 2 730 Fountain Street North Cambridge, ON. N3H 4R7	Contract manufacturing of clinical chemistry system, CT scan, infrared flouresent imaging systems – SPY intra-operative imaging system.
GERMANY	ATS - Marsstrasse 2 D-85551 Heimstetten	Development, manufacture and sales of customer dedicated Automation Solutions for Health Care.
USA	2121 NE Jack London Street Corvallis, OR 97330	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
CANADA	Life Sciences Building 3 730 Fountain Street North Cambridge, ON. N3H 4R7	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
GERMANY	Sortimat - Birkenstrasse 1 - 7 71364 Winnenden Germany	The design, production, sales and service of feeder technology for the pharmaceutical and medical device manufacturing industry
GERMANY	Sortimat - Birkenstrasse 1 - 7 71364 Winnenden Germany	The design, production, sales and service of assembly technology for the pharmaceutical and medical device manufacturing industry
SINGAPORE	38 Jalan Peminpin, #01-01 Wisdom Industrial Building Singapore 577178	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
USA	Sortimat – 5655 Meadowbrook Industrial Court Rolling Meadows, IL 60008	The design, manufacture and service of automated assembly machinery

7.0 PERMISIBLE EXCLUSIONS & NON APPLICABLE ITEMS

The ATS management system scope conforms to the requirements of ISO 9001:2008 with the following permissible exclusions and non applicable items:

7.1 CANADA – APG (BUILDING 2):

Exclusions
In ISO 9001:2008 (E) and ISO 13485:2003 (E):

Clause 7.3, Design and development Planning
Clause 7.3.1 Design & development planning;
Clause 7.3.2 Design and development inputs;
Clause 7.3.3 Design and development outputs;
Clause 7.3.4 Design and Development Review;
Clause 7.3.5 Design and development verification;
Clause 7.3.6 Design and development validation
Clause 7.3.7 Control of design and development changes

The Automation Products Group – Cambridge Division of ATS Automation Tooling Systems does not design or develop products. Customers specify all product characteristics. Our engineering activities are limited to design and development of manufacturing processes, and thus ISO 9001 and ISO 13485 Clause 7.3 shall be applied only where relevant to the design of manufacturing processes.

NON-APPLICABLE ITEMS, ISO 13485:2003(E)

7.5.1.2.1 a), b) ..... Cleanliness of product and contamination control
7.5.1.2.2 ..... Installation activities
7.5.1.3 / 7.5.2.2 ... Particular requirements for sterile medical devices
7.5.3.2.2 ..... Particular requirements for active implantable medical devices and implantable medical devices

Justification for no applicable sections:
APG - Cambridge Division of ATS does not have any customer or regulatory obligations to support contamination control, installation, requirements to support particular requirements for sterile medical devices or for the validation of particular requirements for active implantable medical devices and implantable medical devices thus clauses 7.5.1.2.1, 7.5.1.2.2, 7.5.1.3 / 7.5.2.2, 7.5.3.2.2 under the ISO 13485 standard are not applicable.

7.2 USA – OREGON

ATS Systems Oregon operates under the following industry codes: IAF Code 18 and 19, NACE Code DJ28.3 and DJ28.5, SIC Code 3559 and 3599 and NAICS Code 333295, 333298, and 333999.

EXCLUSIONS

The following sections of the ISO 13485:2003 standard are excluded from the scope of registration:

- 7.5.1.2.1 (a) and (b)…….Cleanliness of product and contamination control
- 7.5.1.2.2……Installation activities
- 7.5.1.3 / 7.5.2.2 ……Particular requirements for sterile medical devices
- 7.5.3.2.2 / 8.2.4.2……..Particular requirements for active implantable medical devices and implantable medical devices

Justification for exclusion of specified sections: ATS Oregon is a supplier to the medical device industry, rather than a medical device manufacturer as such. For that reason, some regulatory requirements do not apply, as noted in the following table:

Excluded Section	Justification
7.5.1.2.1 (a) and (b)	ATS Oregon does not manufacture or distribute sterile medical devices.
7.5.1.2.2	ATS Oregon does not install medical devices. The company does install, commission, and qualify automated systems used to manufacture or test medical devices.
7.5.1.3 / 7.5.2.2	ATS Oregon does not manufacture or distribute sterile medical devices.
7.5.3.2.2	ATS Oregon does not manufacture or distribute sterile medical devices.
8.2.4.2	ATS Oregon does not manufacture or distribute implantable medical devices.

7.3 CANADA – CAMBRIDGE LIFE SCIENCES: BUILDING #3

NON-APPLICABLE ITEMS, ISO 13485:2003(E)

The following sections of the ISO 13485:2003 standard are not applicable to the scope of registration:

- 7.5.1.2.1 (a) and (b)…….Cleanliness of product and contamination control
- 7.5.1.2.2……Installation activities
- 7.5.1.3 / 7.5.2.2 ……Particular requirements for sterile medical devices
- 7.5.3.2.2 / 8.2.4.2……..Particular requirements for active implantable medical devices and implantable medical devices

Justification for exclusion of specified sections: ATS Cambridge is a supplier to the medical device industry and is not a medical device manufacturer. ATS does not have any customer or regulatory obligations to support contamination control, installation, service activities, requirements to support particular requirements for sterile medical devices or for the validation of particular requirements for active implantable medical devices and implantable medical devices therefore, clauses 7.5.1.2.1, 7.5.1.2.2, 7.5.1.3 / 7.5.2.2, 7.5.3.2.2, 8.2.4.2 under the ISO 13485 standard are not applicable.

N/A Section	Justification
7.5.1.2.1 (a) and (b)	ATS Cambridge, building 3 does not manufacture or distribute sterile medical devices.
7.5.1.2.2	ATS Cambridge, building 3 does not install medical devices. The company does install, commission, and qualify automated systems used to manufacture or test medical devices.
7.5.1.3 / 7.5.2.2	ATS Cambridge, building 3 does not manufacture or distribute sterile medical devices.
7.5.3.2.2	ATS Cambridge, building 3 does not manufacture or distribute sterile medical devices.
8.2.4.2	ATS Cambridge, building 3 does not manufacture or distribute implantable medical devices.

7.4 MALAYSIA – PENANG PRODUCTS GROUP

Exclusions:
In ISO 9001:2008 (E):
Clause 7.3, Design and development Planning
Clause 7.3.1 Design & development planning;
Clause 7.3.2 Design and development inputs;
Clause 7.3.3 Design and development outputs;
Clause 7.3.4 Design and Development Review;
Clause 7.3.5 Design and development verification;
Clause 7.3.6 Design and development validation
Clause 7.3.7 Control of design and development changes

The Automation Products Group – Penang Division of ATS Automation Tooling Systems does not design or develop products. Customers specify all product characteristics. Our engineering activities are limited to design and development of manufacturing processes, and thus ISO 9001 Clause 7.3 shall be applied only where relevant to the design of manufacturing processes.

7.5 SORTIMAT GERMANY – WINNENDEN LIFE SCIENCES & PRODUCTS GROUP:

NON-APPLICABLE ITEMS, ISO 13485:2003(E)

The following sections of the ISO 13485:2003 standard are not applicable to the scope of registration:

- 7.5.1.2.1 (a) and (b)…….Cleanliness of product and contamination control
- 7.5.1.2.2……Installation activities
- 7.5.1.3 / 7.5.2.2 ……Particular requirements for sterile medical devices
- 7.5.3.2.2 / 8.2.4.2……Particular requirements for active implantable medical devices and implantable medical devices

Justification for exclusion of specified sections: Sortimat Germnay is not a supplier to the medical device industry and is not a medical device manufacturer. ATS does not have any customer or regulatory obligations to support contamination control, installation, service activities, requirements to support particular requirements for sterile medical devices or for the validation of particular requirements for active implantable medical devices and implantable medical devices therefore, clauses 7.5.1.2.1, 7.5.1.2.2, 7.5.1.3 / 7.5.2.2, 7.5.3.2.2, 8.2.4.2 under the ISO 13485 standard are not applicable.

N/A Section	Justification
7.5.1.2.1 (a) and (b)	Sortimat Germnay Winnenden does not manufacture or distribute sterile medical devices.
7.5.1.2.2	Sortimat Germnay Winnenden, does not install medical devices. The company does install, commission, and qualify automated systems used to manufacture or test medical devices.
7.5.1.3 / 7.5.2.2	Sortimat Germnay Winnenden does not manufacture or distribute sterile medical devices.
7.5.3.2.2	Sortimat Germnay Winnenden does not manufacture or distribute sterile medical devices.
8.2.4.2	Sortimat Germnay Winnenden does not manufacture or distribute implantable medical devices.

7.6 ATS GERMANY – MUNICH GmbH:

NON-APPLICABLE ITEMS, ISO 13485:2003(E)

The following sections of the ISO 13485:2003 standard are not applicable to the scope of registration:

- 7.5.1.2.1 (a) and (b)…….Cleanliness of product and contamination control
- 7.5.1.2.2……Installation activities
- 7.5.1.3 / 7.5.2.2 ……Particular requirements for sterile medical devices
- 7.5.3.2.2 / 8.2.4.2……Particular requirements for active implantable medical devices and implantable medical devices
- 7.5.2……Validation of processes for Production & Service Provisions
- Annex IX to RL 93/42/EWG

Justification for exclusion of specified sections: ATS Germany is a supplier to the medical device industry and is not a medical device manufacturer. ATS does not have any customer or regulatory obligations to support contamination control, installation, service activities, requirements to support particular requirements for sterile medical devices or for the validation of particular requirements for active implantable medical devices and implantable medical devices therefore, clauses 7.5.1.2.1, 7.5.1.2.2, 7.5.1.3 / 7.5.2, 7.5.3.2.2, 8.2.4.2 under the ISO 13485 standard are not applicable.

N/A Section	Justification
7.5.2	The ATS GmbH Munich company excludes the application of the Validation Processes for production and Service delivery. ATS Munich does not influence nor has control in any customer production processes. Therefore, validation cannot be part of the certification. The ATS Munich company also does not provides process services.
Annex IX to RL 93/42/EWG	ATS is not a manufacturer of medical products, there is not a foreseen classification for CE mark. The CE - marking of the ATS Munich GmbH systems is exclusively their own responsibility in connection with a declaration of conformity.
7.5.1.2.1 (a) and (b)	The ATS GmbH Munich company does not manufacture or distribute sterile medical devices.
7.5.1.2.2	The ATS GmbH Munich company, does not install medical devices. The company does install, commission, and qualify automated systems used to manufacture or test medical devices.
7.5.1.3 / 7.5.2.2	The ATS GmbH Munich company does not manufacture or distribute sterile medical devices.
7.5.3.2.2	The ATS GmbH Munich company does not manufacture or distribute sterile medical devices.
8.2.4.2	Sortimat Germnay Winnenden does not manufacture or distribute implantable medical devices.

7.7 ATS SINGAPORE –LIFE SCIENCES:

NON-APPLICABLE ITEMS, ISO 13485:2003(E)

The following sections of the ISO 13485:2003 standard are not applicable to the scope of registration:

- 7.5.1.2.1 (a) and (b)…….Cleanliness of product and contamination control
- 7.5.1.2.2……Installation activities
- 7.5.1.3 / 7.5.2.2 ……Particular requirements for sterile medical devices

- 7.5.3.2.2 / 8.2.4.2……..Particular requirements for active implantable medical devices and implantable medical devices

Justification for exclusion of specified sections: ATS Singapore is a supplier to the medical device industry and is not a medical device manufacturer. ATS does not have any customer or regulatory obligations to support contamination control, installation, service activities, requirements to support particular requirements for sterile medical devices or for the validation of particular requirements for active implantable medical devices and implantable medical devices therefore, clauses 7.5.1.2.1, 7.5.1.2.2, 7.5.1.3 / 7.5.2.2, 7.5.3.2.2, 8.2.4.2 under the ISO 13485 standard are not applicable.

N/A Section	Justification
7.5.1.2.1 (a) and (b)	ATS Singapore does not manufacture or distribute sterile medical devices.
7.5.1.2.2	ATS Singapore does not install medical devices. The company does install, commission, and qualify automated systems used to manufacture or test medical devices.
7.5.1.3 / 7.5.2.2	ATS Singapore does not manufacture or distribute sterile medical devices.
7.5.3.2.2	ATS Singapore does not manufacture or distribute sterile medical devices.
8.2.4.2	ATS Singapore does not manufacture or distribute implantable medical devices.

7.8 USA –sortimat LIFE SCIENCES:

NON-APPLICABLE ITEMS, ISO 13485:2003(E)

The following sections of the ISO 13485:2003 standard are not applicable to the scope of registration:

- 7.5.1.2.1 (a) and (b)……Cleanliness of product and contamination control
- 7.5.1.2.2……Installation activities
- 7.5.1.3 / 7.5.2.2 ……Particular requirements for sterile medical devices
- 7.5.3.2.2 / 8.2.4.2……..Particular requirements for active implantable medical devices and implantable medical devices

Justification for exclusion of specified sections: sortimat USA is a supplier to the medical device industry and is not a medical device manufacturer. sortimat does not have any customer or regulatory obligations to support contamination control, installation, service activities, requirements to support particular requirements for sterile medical devices or for the validation of particular requirements for active implantable medical devices and implantable medical

devices therefore, clauses 7.5.1.2.1, 7.5.1.2.2, 7.5.1.3 / 7.5.2.2, 7.5.3.2.2, 8.2.4.2 under the ISO 13485 standard are not applicable.

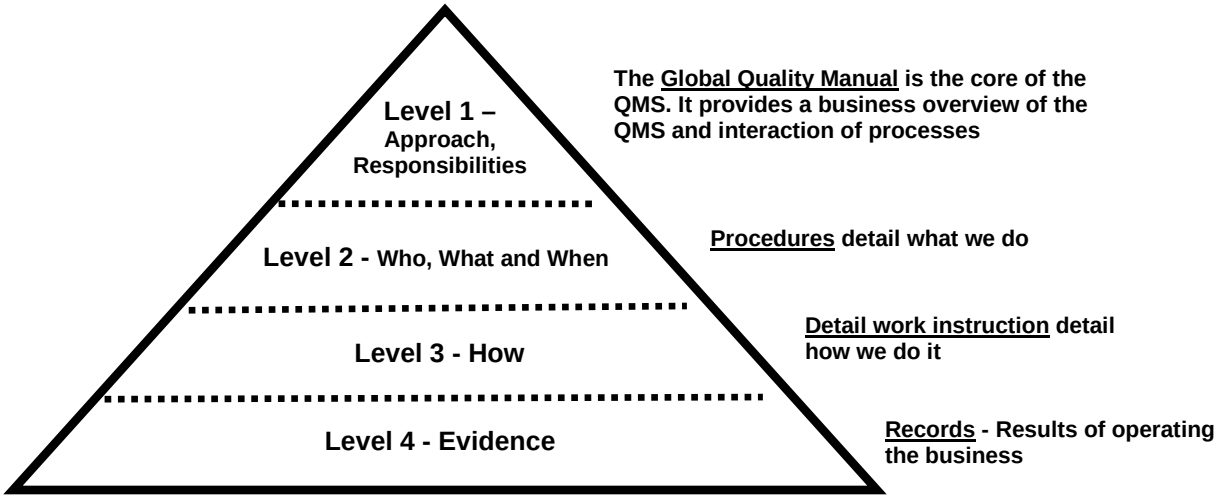
N/A Section	Justification
7.5.1.2.1 (a) and (b)	sortimat USA does not manufacture or distribute sterile medical devices.
7.5.1.2.2	sortimat USA does not install medical devices. The company does install, commission, and qualify automated systems used to manufacture or test medical devices.
7.5.1.3 / 7.5.2.2	sortimat USA does not manufacture or distribute sterile medical devices.
7.5.3.2.2	sortimat USA does not manufacture or distribute sterile medical devices.
8.2.4.2	sortimat USA does not manufacture or distribute implantable medical devices.

7.9 CANADIAN GOVERNING REGULATIONS (as required by contract)

The Canadian Medical Device Regulations – SOR/98-282, FDA GMP 21 CFR part 820 regulations govern the components and assemblies produced by ATS APG for the medical device industry. Audits will be conducted in accordance with the ISO13485 Standard. The following reference documents could be used for guidance, the Canadian Medical Device Conformity Assessment System - CMDCAS and FDA regulations.

8.0 ATS BUSINESS AND QUALITY MANAGEMENT SYSTEM STRUCTURE

8.1 QMS STRUCTURE

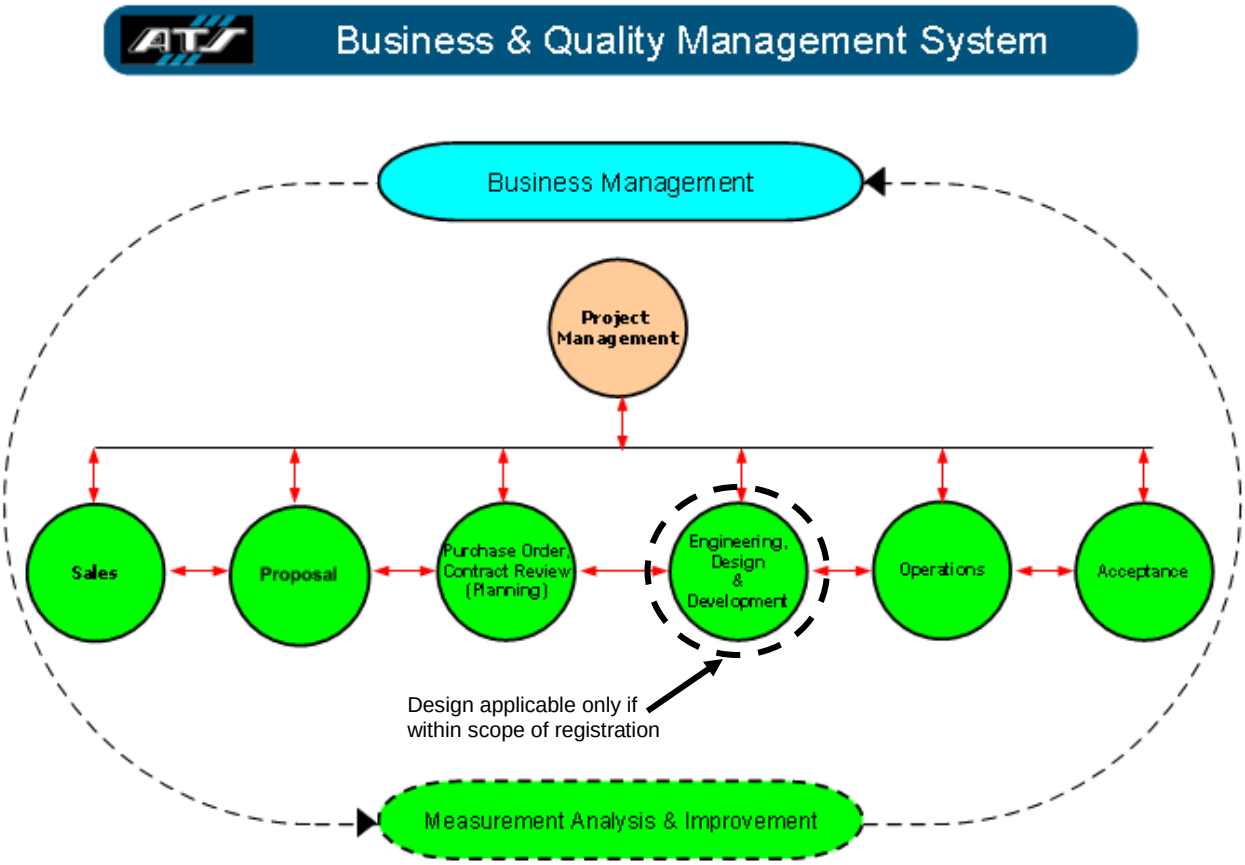


The organization's quality system supports its policy and objectives and is focused on delivering products and services that enhance customer satisfaction through profitable production.

The organization's identified processes are operated under controlled conditions and are monitored, measured and analyzed to ensure ongoing effectiveness and efficiency.

The global process map document #4.1-1-1PFM located on divsionsal Business & Quality Management sites shall identify and correlate all QMS related procedures. All divisional specifc relationships between ISO 9001:2008/ISO 13485:2003 (applicable to 13485 business units only) shall be maintained by each respective site to supplement this manual.

Document # PFM 4.1-1-1PFM:



Global ATS procedures shall be implemented and enforced by each site. Key Quality metrics will be reported to the Global Quality Director on scheduled intervals and monitored for performance.

The ATS Global Director of Quality reserves the right to audit any ASG facilities as required or deemed necessary by Executive Management.

8.2 DOCUMENTATION REQUIREMENTS

The Quality System documentation includes:

- A Quality Policy Statement
- Business Plan, including Quality Objectives
- Global Quality Management System manual
- Documents needed by the organization to ensure the effective planning, operation and control of its processes (defined by each division), including work instructions and forms
- Records required by ISO 9001:2008 and ISO 13485:2003

8.2.1 The Global Quality System documentation includes the following documented procedures required by ***ISO 9001:2008*** and ***ISO 13485:2003*** (reference section 10):

- **C4.2.3 Global Document Management** (refer to ISO 9001:2008 / ISO 13485:2003, section 4.2.3 Control of Documents)
- **C4.2.4 Global ISO Record Control Requirements** (refer to ISO 9001:2008 / ISO 13485:2003, section 4.2.4 Control of Records)
- **C8.2.2 Global Quality Management System Program** (Internal Audit) (refer to ISO 9001:2008 / ISO 13485:2003, section 8.2.2 Internal Audit)
- **C8.3 Global Control of Non-Conforming Material** (refer to ISO 9001:2008 / ISO 13485:2003, section 8.3 Control of Non-Conforming Product)
- **C8.5.1 Global Continual Improvement Process** (refer to ISO 9001:2008 / ISO 13485:2003, section 8.5.2 Corrective Action)
- **C8.5.1 Global Continual Improvement Process** (refer to ISO 9001:2008 / ISO 13485:2003, section 8.5.3 Preventive Action)
- **C8.5.1 Global Continual Improvement Process** (refer to ISO 13485:2003, section 8.2.1 Feedback)
- **C8.5.1 Global Continual Improvement Process** (refer to ISO 13485:2003, section 8.4 Analysis of Data)

8.2.2 The Quality System documentation includes the following documented procedures/processes required by ***ISO 13485:2003*** and shall be maintained by each applicable divison:

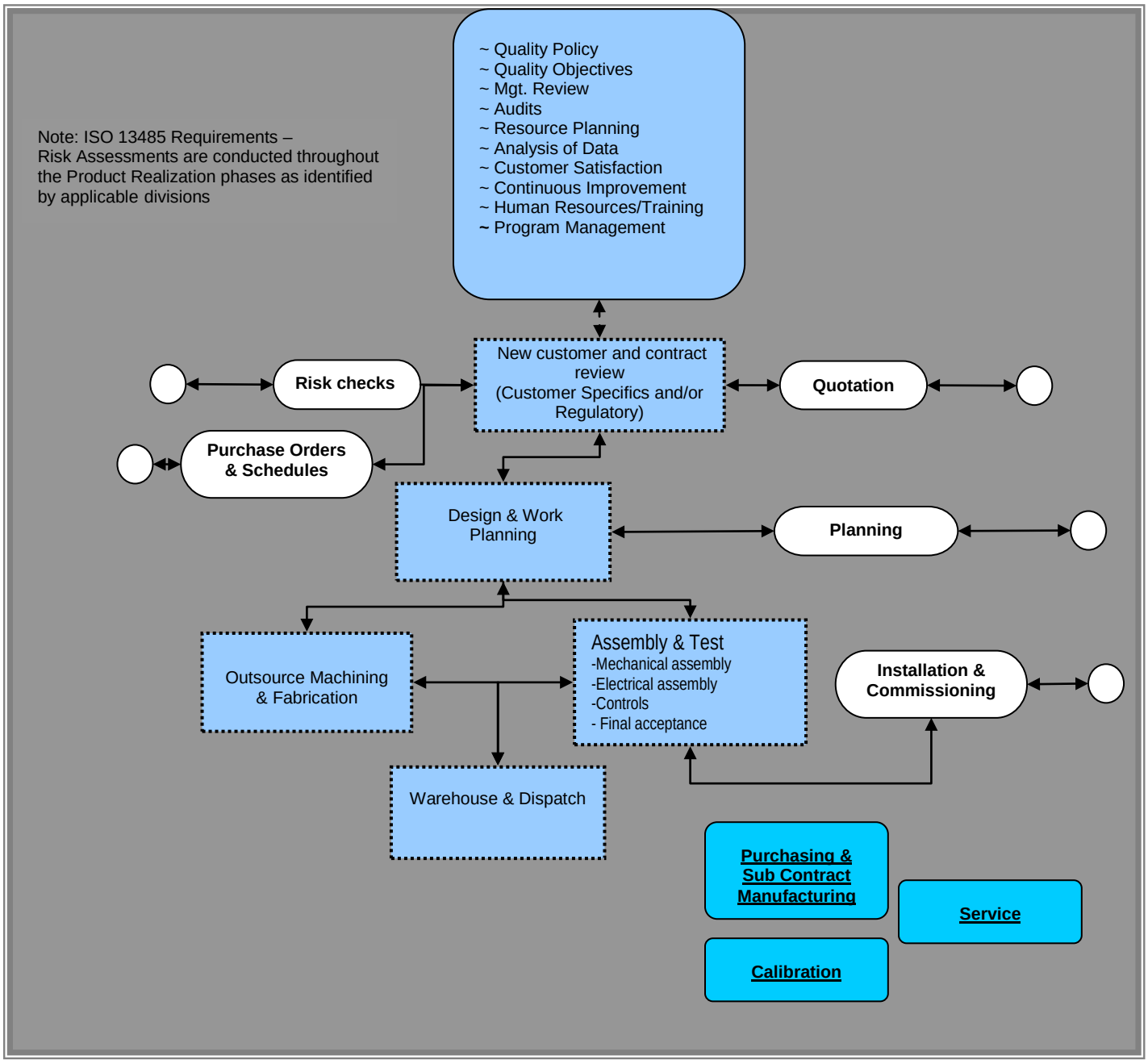
Documented Procedures:

- Project Management; Electrical Design; Mechanical Design; Software Design (refer to ISO 13485:2003, section 7.3.1 Design and Development Planning)
- Purchasing (refer to ISO 13485:2003, section 7.4.1 Purchasing Information)
- Servicing Activites (refere to ISO 13485:2003, section 7.5.1.2.3)
- Validation (refer to ISO 13485:2003, section 7.5.2.1 Validation of Processes for Production and Service Provision)
- *Particular Requirements for Sterile Medical Devices – EXCLUDED (refer to ISO 13485:2003, section 7.5.2.2)*
- Product Identification; Return of Medical Devices; Control of Non-Conforming Material (refer to ISO 13485:2003, section 7.5.3.1 Identification)
- Product Serialization and Nameplate Specification; (refer to ISO 13485:2003, section 7.5.3.2.1 Traceability)
- Shelf Life Materials (refer to ISO 13485:2003, section 7.5.5 Preservation of Property)
- Calibration (refer to ISO 13485:2003, section 7.6 Control of Monitoring and Measuring Devices)
- Advisory Notice (refer to ISO 13485:2003, section 8.5.1 Advisory Notice)

Documented Requirements:

- Clean Room Requirements (refer to ISO 13485:2003, section 7.5.1.2.1 Cleanliness of Product and Contaminiation Control)
- *Installation of Medical Device - EXCLUDED (refer to ISO 13485:2003, section 7.5.1.2.2 Installation Activites*
- Preventive Maintenance (refer to ISO 13485:2003, section 6.3 Infrastructure)
- Risk Management (refer to ISO 13485:2003, section 7.1 Planning of Product Realization)
- ESD, Work Environment, Health & Safety (refer to ISO 13485:2003, section 6.4, Work Environment)

9.0 PROCESS INTERACTIONS OVERVIEW (Reference scope for applicable items per division)



10.0 DOCUMENT RELATIONSHIP MATRIX FOR KEY GLOBAL DOCUMENTATION

Relationship between the organization's documented procedures and the requirements of ISO 9001:2008 & ISO 13485:2003

Document Ref No.	Global Quality Management Procedures	Standard Cross Reference	Standard Cross Reference
		ISO9001	ISO 13485
C4.3-1M	**Global Quality Manual**	**4.2.2**	**4.2.2**
C7.4-1-1M	**Global Supplier Quality Manual**	**7.4.1, 7.4.2**	**7.4.1, 7.4.2**
C4.2.3	**Global Document Management**	**4.2.3**	**4.2.3**
C4.2.4	**Global ISO Record Control Requirements**	**4.2.4**	**4.2.4**
C5.6	**Global Management Review Process**	**5.6**	**5.6**
C7.4.1	**Global Supplier Performance Program**	**7.4, 8.4, 8.5.2, 8.5.3**	**7.4, 8.4, 8.5.2, 8.5.3**
C7.4.1-2P	**Global Supplier Development & Evaluation**	**7.4.1**	**7.4.1**
C8.2.2	**Global Quality Management System Program**	**8.2.2**	**8.2.2**
C8.3	**Global Control of Nonconforming Product**	**8.3**	**8.3**
C8.5.1	**Global Continual Improvement Process**	**8.5.1, 8.5.2, 8.5.3, 8.2.1**	**8.5.2, 8.5.3, 8.5.1, 8.2.1**
C8.5.1	**Global Continual Improvement Process**	**8.4**	**8.4**
C7.3.6-1P	**Global Acceptance Test Plan**	**8.2.4, 7.3.6, 7.5.1**	**8.2.4, 7.3.6, 7.5.1.1**