



Changzhou Intl. Trade & Enterprises Cooperative Co., Ltd.

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Quality Management System Summary

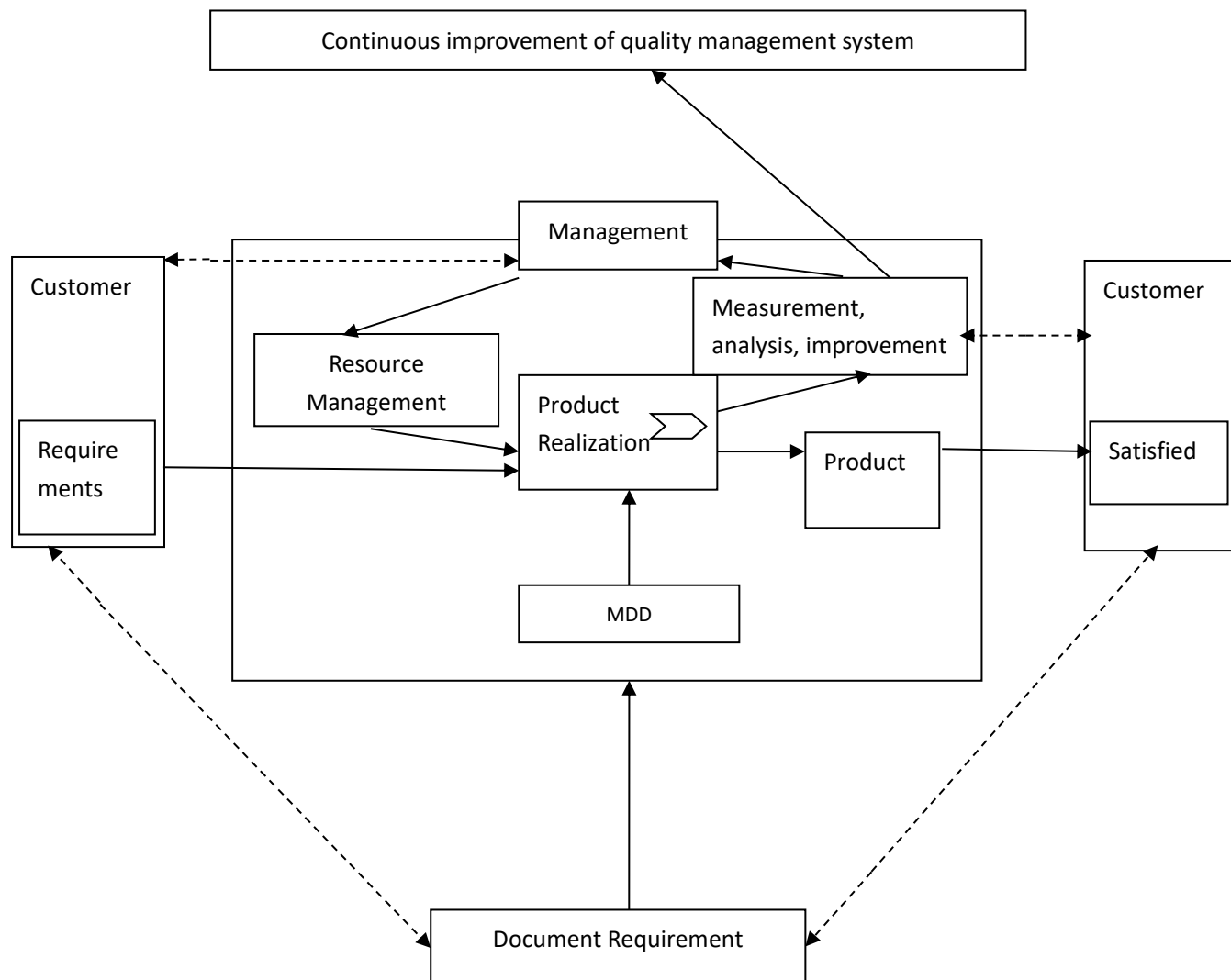
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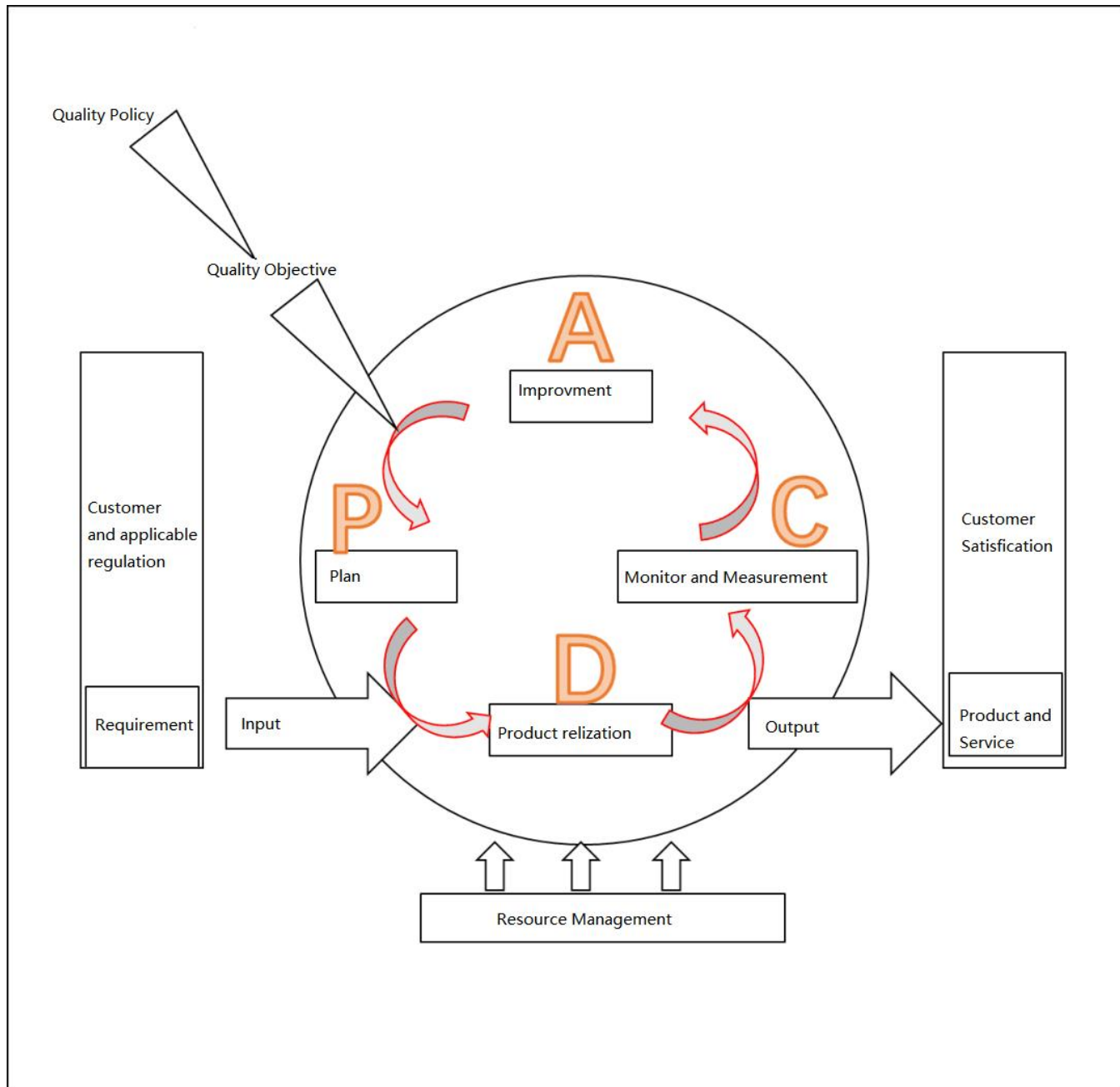
1. Scope

Changzhou Intl. Trade & Enterprises Cooperative Co., Ltd (CITEC) is established in year 2000 and focus on Design and Development, Manufacture and Distribution of Endoscopic Instruments, Non-vascular Stents, Surgical Staplers, Orthopaedics Implantable Devices; Manufacture and Distribution of Clean Connecting Tubes.

2. Processes

Quality Management System ISO13485: 2016



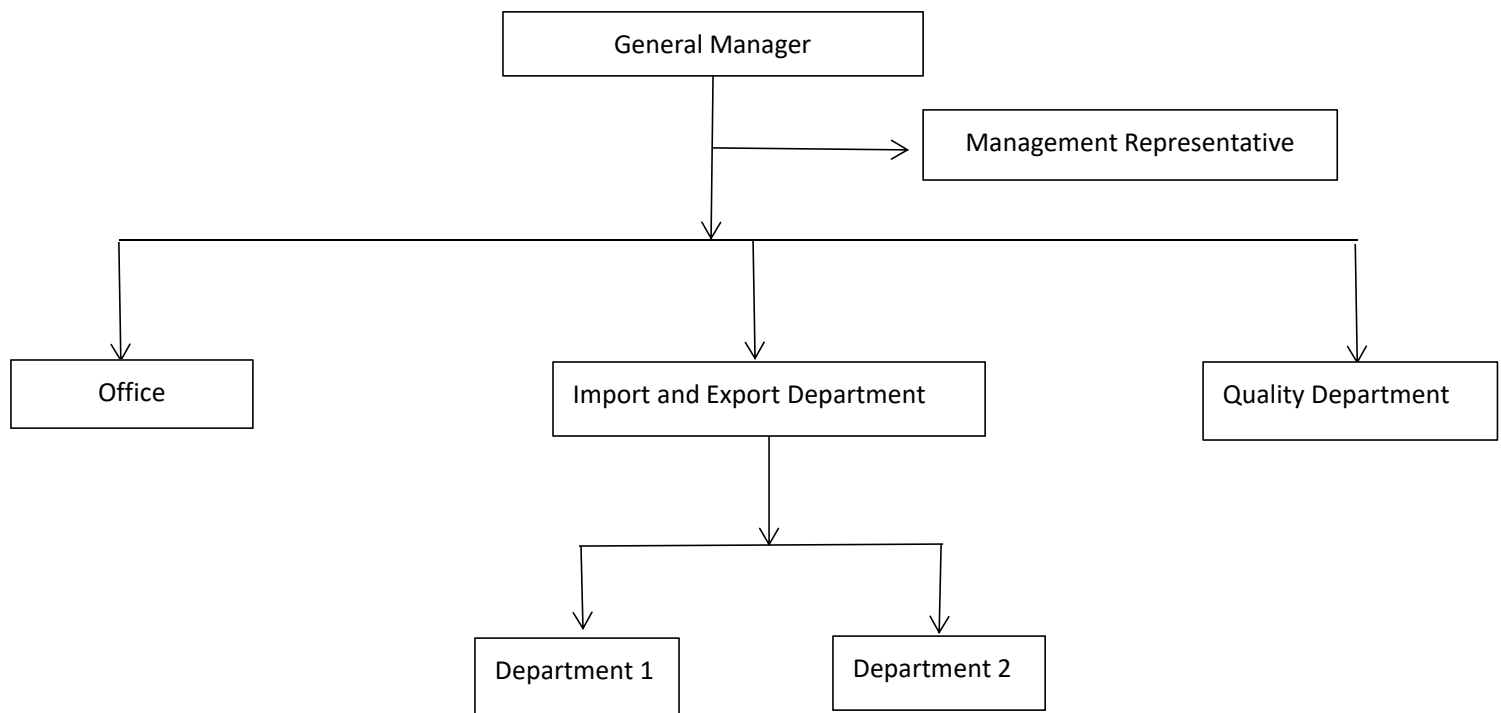


The Plan Do Check Act cycle shall apply to all processes at CITEC

3. Leadership and Commitment

General manager is committed to the Quality Management System, with the Management Representative holding responsibility and authority for the systems.

4. Organization Chart:



5. Organization Roles, Responsibilities

The general quality policy and direction of the company shall be formulated, issued and implemented by the general manager.

The General Manager ensures that quality objectives are established at the relevant functions and levels of the company.

In order to meet the quality objectives and establish, implement and maintain the effectiveness of the quality management system, the general manager shall plan the quality management system in the following aspects:

The General Manager shall ensure that the responsibilities and authority within the company are defined, documented and communicated. According to the needs of the operation of the company's quality management system, the general manager sets up the organization of the company's quality management system, defines the functions of quality management, and defines the responsibilities and authority of each organization. Responsibilities and authority of all departments and personnel of the Company.

The General Manager shall review opportunities for improvement and requirements for changes in the quality management system to ensure the continued suitability, adequacy and effectiveness of the quality management system.

The office will compile the decisions made by the management review and the measures proposed into a corrective plan, in which the responsible department and corrective time are specified. After the approval of the management representative and the general manager, the corrective plan will be issued to all functional departments in the form of a document. The management representative is responsible for organizing the tracking and verification of the implementation.

6.Policies

A Quality Policy is maintained on the server and communicated to all staff during induction. It is reviewed as part of the Management Review process.

