PROPOINT

Translation of the Propoint Quality Manunal from Swedish to English, based on the document Kvalitetsmanual, Doc ID: 8530 200, version M.
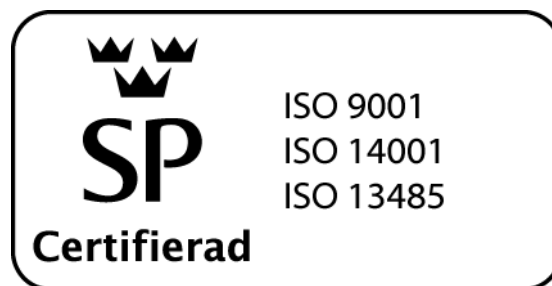
Quality Manual

SS-EN ISO 9001:2015

SS-EN ISO 13485:2016

SS-EN ISO 14001:2015

Korea's Medical Device Act and MFDS (Ministry of Food and Drug Safety) Notification - KGMP

SP Certifierad
ISO 9001
ISO 14001
ISO 13485

~~**Dok ID: 8530 200**~~
~~**Revision M**~~

Business

The business of Propoint is to produce electronics in form of printed circuit boards and to assemble them into finished products based on our customer's needs. Propoint is not a product owner but produces according to customer product specifications.

Organisation and responsibilities

The organization of Propoint is described in a organization chart.

Individual job descriptions describe the responsibilities and powers of staff at Propoint. Competence levels for staff are stated in personal records. A competence matrix for production personnel describes the skill levels achieved for each production staff as well as targets regarding increasing the level of competence.

The Propoint management team has the overall responsibility for leading the company and developing, implementing and continuously improving the quality management system. The management team also has the overall responsibility for ensuring that the organization works customer-focused to achieve high customer satisfaction, has the necessary resources for equipment, infrastructure and competent staff, required work environment, and that the company complies with the requirements in the standards the company had chosen to follow.

The Propoint management team consists of the following functions.

- Managing Director
- Deputy Managing Director and Personnel Manager
- Site Manager
- Quality and Environmental Manager
- Marketing Manager
- Production Manager
- Purchasing Manager

The Quality and Environmental Manager is appointed to be the quality management representative. This includes powers to ensure that the processes needed for the quality management system is documented, report to the management team regarding the effectiveness and the need for improvement of the quality management system, and to promote the awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

All employees must follow the quality management system regulations and actively work to improve these for increased quality of work and products.

Management system

The Propoint management system covers the entire Propoint business. The Propoint operation is carried out within the physical boundaries of Faktorvägen 13, Kungsbacka, Sweden.
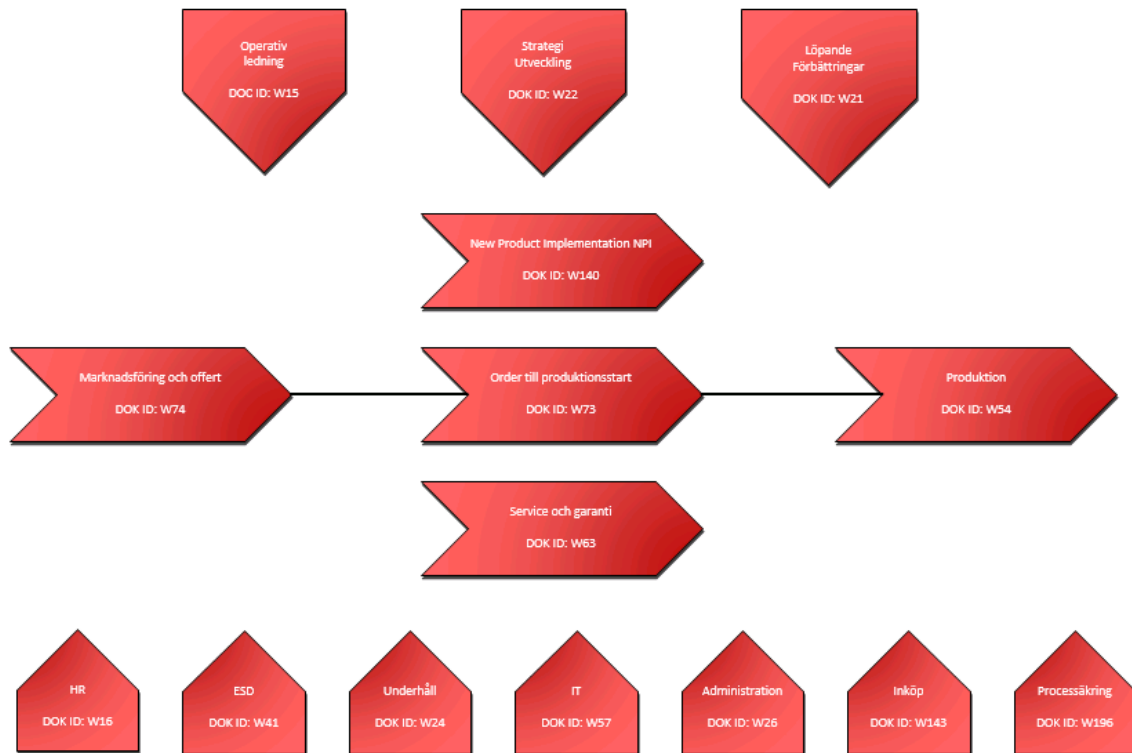
The Propoint management system has a process-oriented structure with an overall process map of the company's processes and how they interact. In cases where a subprocess consists of many successive activities carried out by many persons or departments, there is an underlying subprocess chart that specifies the order of these activities and the company function that will implement it.

For each managing process, main process and supporting process, there are documented procedures and practices which describes the activities that are performed in the different processes. From the

various activities there are links to underlying instructions, when necessary, which describe the workflow in more detail.

In the various processes there are also references to the forms, checklists and templates etc used in the work of the various processes.

The management system is published on the Propoint Intranet, for easy access for all employees.

The processes in Propoint quality management system and their reference documents.

Managing processes

Propoint has three managing processes which guide the workforce's work in accordance with the corporate management targets.

Operational Management

The Operational Management section describes the management and follow-up of daily work. This section contains routines and information about policies, goals, organization, meeting structures, external standards, and other requirements, laws and environments that affect Propoint.

Strategy and Development

The Strategy and Development section covers the workflow of the company's long-term strategies.

Continuous improvement

The Continuous Improvement section describes how Propoint is working on continuous improvements and how these improvement opportunities are identified. This section includes Audits (internal and external), customer feedback, management of external and internal deviations, management review etc.

Main Processes

Propoints main flow is divided into three parts, Marketing and quotation, Order to start of production start and Production. These three flows follow in sequence and interact in three steps, from the first customer contacts to the delivery of goods.

In parallel with these three processes, we also have the processes Service and Warranty and New Product Implementation NPI.

Marketing and Quotation

The section describes the flow of the Marketing and Quotation process, from the first customer contacts, to sending the customer a quote and follow-up. The process describes working methods for reviewing customer requirements, how processing and filing customer documentation is done, as well as purchase related work related to the quotation and its accompanying purchasing requirements to create a valid quotation for the customer.

Order to start of production

The section describes the flow in the process Order to start of production, from customer sending Propoint an order to components being ready for production. The process describes working methods for changes in customer requirements and documents, additional customer-owned production equipment, order management in MPS, preparation of product specific instructions, updating purchasing parameters for the actual order, purchasing and inspection of incoming material.

Production

The section describes the flow in the process Production, from detailed planning of production to delivery to customers. The process describes working methods for identification of products and their production status, working methods for the different production sections and delivery to stock and customers.

Service and Warranty

The section describes the workflow of the process Service and Warranty, from incoming service and complaint cases to the return of repaired products to customers. The process is largely influenced by the process Continuous Improvement.

New Product Implementation NPI

The section describes the overall flow for the process New Product Implementation NPI, to give feed-back to customers regarding the producibility of new products.

Supporting processes

A number of supporting processes help the other processes by creating conditions to work as optionally as possible.

HR

The section describes personnel related activities such as recruitment, introduction of new employees, competence development and employment termination.

ESD

The section ESD describes ESD, Electro Static Discharge, what ESD is and how Propoint creates an EPA, ESD Protected Area, for safe production of products regarding ESD.

Maintenance

The section includes non-processual service instructions such as calibration.

IT

The section covers the IT environment of Propoint, including back-up of data.

Administration

The section describes how documents are handled, such as changes, approval, filing and education in documents.

Purchasing

The section describes working methods for supplier development and other purchasing related work not directly linked to any main process.

Process assurance

The section describes changes in the internal production processes (not related to product specific processes) and the work-flow of implementation of new production equipment to secure quality, effectiveness and safety for personnel.

Exclusions

Chapter 7.3

Chapter 7.3 is excluded and is not handled in the management system of Propoint. The reason for this is that Propoint only produces products not designing products.

Chapter 7.5.2

Chapter 7.5.2 is excluded and is not handled in the management system of Propoint. The reason for this is that Propoint don't produce products which is affected by these requirements.

Chapter 7.5.3

Chapter 7.5.3 is excluded and is not handled in the management system of Propoint. The reason for this is that Propoint don't perform installation activities.

Chapter 7.5.5

Chapter 7.5.5 is excluded and is not handled in the management system of Propoint. The reason for this is that Propoint don't sterilize products.

Chapter 7.5.7

Chapter 7.5.7 is excluded and is not handled in the management system of Propoint. The reason for this is that Propoint don't sterilize products.

Chapter 7.5.9.2

Chapter 7.5.9.2 is excluded and is not handled in the management system of Propoint. The reason for this is that Propoint don't produce implantable products.

Changelog

Utgåva	Datum	Beskrivning	Sign

2	05-01-25	WM-data borttaget. Bolaget är privatägt	PN
3	09-09-10	Ny begrepp mätinsamling	PN
4	10-10-29	Uppdateringar	PN
5	11-04-14	Organisationsändring	PN
F	14-06-04	Helt omarbetad version	JN
G	14-08-20	Tillägg första sidan: Korea's Medical Device Act and MFDS (Ministry of Food and Drug Safety) Notification - KGMP	JN
H	14-08-20	Tillägg av uteslutningar	JN
I	15-04-29	Teknisk utveckling samt NPI tillagt.	JN
J	17-02-02	Justering för ISO 14001	JN
K	18-05-02	Borttagning av teknisk utveckling. Ändring av standardutgåvor. Uppdatering av exkluderingar.	JN
L	18-06-19	Tillägg av Verksamhet samt beskrivning av ledningssystemets omfattning.	JN
M	18-08-16	Tillägg av Organisation och ansvar, Processkarta uppdaterad samt förtydliganden i flertalet processbeskrivningar.	JN