Executive Management Responsibilities

Commitment of Executive Management

I agree with the need to build and maintain an operational quality management system that can be applied to the activities of the company, in compliance with the requirements of the ISO 9001 and ISO 13485 standards and the EU medical device directive 93/42/CEE.

Our quality management system is consistent with Defymed's quality policy and includes the following activities:

- Medical device research, development & manufacturing activities

I am committed to:

- Organizing human, financial, organizational and technical resources necessary to build an effective quality system within the company.
- Training the company's staff in science, technology and quality management to guarantee a perfect control of the products developed by the company.
- Promoting the quality approach of the company and ensuring it is respected and adequate through management reviews and audits.
- Involving the whole staff in implementing improvement actions.
- Complying with regulatory, contractual requirements and other identified requirements.
- Controlling product traceability.
- Controlling risk management throughout the entire life of our medical devices.
- Ensuring the sterility of our devices by controlling special processes.

Our quality approach concerns every partner of Defymed and shall be applied on a daily basis. All partners must act in the common interest and engage in a continuous improvement process to provide customer and partner satisfaction.

Séverine SIGRIST
CEO of Defymed

Version 5
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Quality Policy

Defymed's quality policy is structured around 4 main points:

- Bringing customer and prospect satisfaction by understanding and meeting their expectations:
    - To identify potential customers and ensure the implementation and monitoring of the service delivery.
    - To ensure that service delivery is compliant and customers are satisfied.
- Adding value to our products by mobilizing the technical skills of the staff and complying with applicable regulatory authorities:
    - To acquire and maintain a high level of technology and expertise to ensure that our products comply with the requirements of the ISO 9001 and ISO 13485 standards and are safe and fit for their purpose.
    - To ensure the health safety of patients and end users by controlling the manufacturing of our devices (including their controls and release) and organize appropriate methods of identification and traceability of devices that have been released.
    - To prove to the relevant authorities that our products are conforming and complete the technical file of the product.
- Optimizing the performance of the company:
    - To implement and ensure a coherent strategy to ensure the long-term existence of the company.
    - To look for potential customers (partners, investors) and organize the carrying out of research and development activities to ensure tasks and deliverables, defined in the original development plan, are successfully completed and promote projects within a quality management system.
- Organizing an appropriate continuous improvement methodology:
    - To assess the performance and quality of processes and thus their improvement through a continuous assessment process.
    - To provide our partners with the tools they need to optimize the processes of the company under their own responsibility.

Séverine SIGRIST
CEO of Defymed