

## MANAGEMENT STATEMENT

---

It is essential for the Chairman of anthogyr company to implement and keep operational a Quality Management System that applies to the company activities and meets the EN ISO 9001:200, EN ISO 13485:2003 standards + AC:2007, the European Directive 93/42/CEE appendixes II point 3, V point 3 and VII, the European Directive 2007/47, as well as the Japanese Departmental Order n°169 :2004 from MHLW (Ministry of Health, Labour and Welfare), and lastly the referential 21 CFR Part. 820 (FDA).

The Quality Management System, as part of the anthogyr quality policy, is in charge of improving the services provided by the company by constantly adapting the following principles:

- Design of reliable and innovative products thanks to effective internal control over risk management;
- Understanding internal and external customers' requirements and evaluating their satisfaction level;
- Involvement, motivation and education of the staff;
- Total involvement so as to reach quality/cost/service targets and to sell cost-effective products;
- Rationalizing the company's structure;
- Using processes to manage the company's activities;
- Continuous evaluation of the processes, and their cost;
- Working closely with suppliers for mutual benefit.

So as to implement and keep operational the Quality Management System, the Chairman authorizes and delegates the QUALITY and REGULATORY AFFAIRS MANAGER (as he is the Management Representative and Customer Representative) to keep operational the company's Quality Management System. The QUALITY and REGULATORY AFFAIRS MANAGER is in charge of using it properly and keeping the General Management informed about the system efficiency and possible improvements to be brought. Finally, the Managing Director has to make sure that anthogyr is in compliance with standards and laws in force. He is also responsible for stopping any activity or process that may alter the product quality and security or the efficiency of the Quality Management System.

Our commitment to quality is clearly stated in our quality policy, which is determined by our customers' expectations (present and prospective client), by strengths and weakness of our organisation, and by the concrete targets that our team is associated to.