



Annex VII. Quality Policy

Código: MC (Anexo VII)
Revisión: 03
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The objective of the Quality Management System of TERRATS MEDICAL S.L. is to establish the criteria through which our activities must be developed, in order to:

- ✓ Satisfy the requirements, both to our clients, as well as meet legal requirements, and adhering to standards that are applicable to us: Directive 93/42/CEE and REGULATION (EU) 2017/745 on Medical Devices and the Standards UNE EN ISO 9001: 2015 and UNE EN ISO 13485: 2016, SOR 98 282; MHLW MO169:16; 21 CFR 820.20(b),
- ✓ Detect opportunities for improvement and undertake actions aimed at optimizing the operation of our company.
- ✓ Define the context of TERRATS MEDICAL S.L. by evaluating the weaknesses, threats, strengths and opportunities, and respond accordingly.
- ✓ Identify the risks to TERRATS MEDICAL S.L., by analysing, assessing, and treating those that are considered most significant.
- ✓ Post-marketing follow-up, market surveillance and control with trend analysis.
- ✓ Risk management on the product and residual risk assessment.

Consequently, the Management of TERRATS MEDICAL S.L. commits to:

- ✓ Review/ Modify / Define the Quality Objectives by providing the resources required to achieve them.
- ✓ Design and maintain management by processes, in which we will measure their effectiveness.
- ✓ Review the adequacy and suitability of the human and material resources to achieve the conformity of our products and, as to the extent possible, maintain a high level of satisfaction with our customers.
- ✓ Motivate all our staff to comply with the provisions of our Quality Management System, as this is a fundamental element to maintain / improve our good image as a company.
- ✓ Apply our Quality Management System as an additional business management tool, periodically reviewing its implementation and effectiveness and establishing the mechanisms for its Continuous Improvement.

Reviewed 03/2021

Signed: Roger Terrats Bes