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## QUALITY POLICY

MADESPA's management, being aware of the current trends regarding quality, keep on in this new stage with Quality as a uniting element of all our efforts.

***MADESPA, dental products manufacture, and distributor of dental instruments and equipment, wish their Quality System to meet all the requirements established by the standard ISO 9001:2015 "Quality Management Systems. Requirements" and the standard ISO 13485:2016 "Medical Devices. Quality Management Systems. Requirements for regulatory purposes".***

The Management objectives regarding Quality are:

- To provide our customers with products that meet their requirements (quantities, delivery deadlines, quality requirements).
- To provide our customers with products manufactured by MADESPA that comply with the applicable law, especially with the Regulation (EU) 2017/745 of Medical Devices.
- To address the organization according to the different processes that set it up, considering the related risks and opportunities to keep effectiveness and promote the continual improvement of the Quality System for the compliance of all the requirements.
- To carry out the Risk Management of the manufactured medical devices in compliance with ISO 14971:2019.
- To adjust our operating procedure to adapt ourselves to technological changes, legal requirements, competence and the market.
- To build reliable and respectful relationships with our customers, to become their allies, to be flexible to provide them a service that meets their expectations and to respond to their specific needs so that they feel satisfied.

Those specific and quantifiable objectives, in line with the Quality Policy that the Management has established for next year, are included in the system review record that will be carried out at the end of the year.

Consequently, the Management is committed to provide all the necessary material and human resources for the fulfilment of these objectives, and it establishes a Quality System as it appears in this Manual, that is intended to be the governing principle of our acts and the base document for the realization of our activities.

In the same way, everyone at MADEPSA has the responsibility, within their field of action, to apply the governing principles of this Manual and to contribute with their ideas and actions to the achieving of these governing principles.

The implementation and monitoring of such system is assigned to the Quality Supervisor, who holds the necessary authority to assure that all the Quality requirements defined in this Manual, in the international applicable law and by our customers, are fulfilled.

Fdo. Juan José Serafín Pace  
General Manager