QUALITY POLICY

The Management of Endotecnica s.r.l. has established to introduce a certified quality management system in the company with the aim of increasing its ability to continuously supply products and services that satisfy the customer, corresponding to their real needs and comply with the applicable mandatory requirements.

The international standard of the quality management system for the activity carried out by Endotecnica s.r.l. is dictated by the supranational standards on Quality Management Systems - UNI EN ISO 9001:2015 and on Quality Management Systems for Medical Devices - UNI CEI EN ISO 13485:2021, standards to which, in accordance with the guidelines given, the same has decided to adapt.

The quality policy of Endotecnica s.r.l. it is developed with a constant comparative analysis of the context, both internal and external to the organization, of which the three main components have been segmented, namely the physical Aspects, the social Aspects and the economic Aspects. For each of these three macro-areas, appropriate business processes have been formed, aimed at operationally implementing the strategies used.

The consideration, then, of the relevant interests of all the parties involved in one's own activity has led to the definition of relational schemes between the context and the parties involved capable of facilitating the identification and adaptation of the main processes and related objectives.

The management of our main processes and the influences of the corporate contexts or superficial parts is further completed with the forecasts of risk-recovery actions, planned through the assessment of the severity and probability of the related risks according to the

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reference supranational guidelines - UNI ISO 31000: 2018 ("Risk management - Principles and guidelines").

Pursuant to EU Regulation 745/2017 ENDOTECNICA s.r.l. declares to assume the role of

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and to comply with the obligations established for this figure by the Regulation.

The purposes of the certifications are:

according to 9001:2015: Marketing, installation and assistance of medical devices, including endoscopes for medical applications. Marketing, installation and assistance of borescope systems for industry.

according to 13485:2021: Marketing, installation and service of medical devices, including endoscopes for medical applications

The main quality objectives are as follows:

a) achieve and maintain a quality of the product and of the service provided, such as to continuously satisfy the requirements of the customer and the interested parties, the applicable mandatory requirements (in particular the EU Regulation 745/2017 for the product and Regulations 9001:2015 and 13485:2021 for the system), customer and stakeholder satisfaction;

b) ensure adaptation to the evolution of the legislation, especially after the entry into force of the EU regulation on medical devices (2017/745);

c) pursuing continuous improvement in the conduct of the company business, so that this improvement is perceived externally and internally in terms of greater customer satisfaction with the products and services provided;

d) guarantee customers and all interested parties the safeguarding and protection of personal data and of a sensitive or judicial nature, observing the principles of lawfulness, limitation, minimization, accuracy, integrity and confidentiality, dictated by the "general regulation for the protection of personal data" GDPR 2016/679;

e) ensure an effective degree of communication of this corporate policy statement, using appropriate methods and tools. The recipients of this communication also include the interested parties, in particular the people of the organization and the subjects of the context closest to it;

f) guarantee the mandatory requirements set forth by Legislative Decree 231/01 according to the organizational, management and control model already adopted by Endotecnica s.r.l. from 29 February 2016.

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A correct development of the communication process implies the knowledge, the involvement and the contribution of every function and person of the organization, within the scope of their competences, in the implementation and achievement of the defined objectives.

The AU of Endotecnica s.r.l. undertakes to:

¬ translate the objectives expressed in this policy into a measurable way

¬ annually provide the level of results achieved, specifying the new objectives for the following period.

Turin, 24 May 2023

CEO

ENDOTECNICA S.R.L.
Boggio Marzet Dott.Giancarlo

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