



TITLE/TITOLO	Quality Policy
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Rev.	Date/Data	Issued by Emesso da	Verified and approved by Verificato ed Approvato da	Description of changes Descrizione delle modifiche
0.0	01.06.2017	Quality Manager	Top Management	First issue/Prima emissione
0.1	22.03.2018	Quality Manager	Top Management	Change of company name/Modifica ragione sociale
0.2	15.02.2021	Quality Manager	Top Management	Update JAT MDR/Aggiornamento JAT MDR
0.3	24.03.2022	Quality Manager	Top Management	Specific reference to R-UE 2017/745

MSM-03 en	Rev. 0.3	I/I
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MTIC INTERCER S.r.l. (hereafter MTIC) is a conformity assessment body working in the field of voluntary and mandatory certification of systems, products, services and persons.

The sources of financing of the organism are attributable only to the certification, inspection and test activities provided to its customers. The body does not receive funding from any third party.

Voluntary activities can be carried out in the field of both accredited and not accredited field under approval of customers.

The conformity assessment body carries out the tasks entrusted to it in an independent and impartial way, for the benefit of society and the global economy. Each activity is managed with the same procedures both nationally and internationally.

MTIC is aware of the importance of impartiality in carrying out its conformity assessment activities, manages the risks for its impartiality and ensures the objectivity of compliance assessment activities. ISO/IEC 17021-1 requirements apply to management system certification activities, ISO/IEC 17065 requirements apply to product and service certification; requirements of ISO/IEC 17024 apply to persons certification; requirements of ISO/IEC 17020 apply to inspection activities; requirements of ISO/IEC 17025 apply to test activities.

Within its activities, MTIC respects national and international standards, applicable laws and regulations of the accreditation bodies and notifying authorities. With particular reference to the role of Notified Body, it adopts the principles of the new European legislative framework defined starting from Regulation 765/2008/EC, Decision 768/2008/EC and Regulation (EC) 1221/2009 and Regulation UE 2017/745 for the specific area of conformity assessment of medical devices, in compliance with the single harmonization legislation of Union referable to products subject to CE certification and marking for which it has obtained authorization and notification to the European Commission from the relevant authorities as reported in its statute where the corporate purpose is described.

This is achieved through the adoption of a documented quality management system whose objective is to demonstrate how the Organization assimilates the requirements of the above documents indicated by transforming them into operational processes that ensure constant compliance.

The adequacy of the management system and the effectiveness in achieving the goals is periodically reviewed by the top management and approved by the committee for safeguard impartiality. Top management has full responsibility and authority to ensure compliance with all that is stated in the management system documents.

MTIC's **OBJECTIVES** are:

- Prepare, maintain, apply and manage a quality management system, appropriate for the nature, sector and scope of its conformity assessment activities, capable of support and demonstrating constant compliance with the requirements of the previously indicated documents and in particular of EU Regulation 2017/745 for the specific area of conformity assessment of medical devices as well as allowing the achievement of the objectives indicated in this document
- Provide a service that stands out for its professionalism, efficiency, delivery times and price/performance ratio;
- Reaching, maintaining, and constantly increasing customer satisfaction, which is the top priority for the certification body and fundamental to maintain competitiveness in markets around the world.
- Constantly improve the level of its services.

MTIC commits to adopt the following points:

- Consistently apply the requirements of its management system, standards, technical reference regulations, and applicable laws to determine the times, the modalities and costs of the activities;
- Encourages all organizations, not just customers, to seek continuous improvement and assume greater responsibility for their work processes;
- Carries out its activities independently of political and economic interests, is not subject to external influences and follows non-discriminatory policies towards the subjects interested in its services;
- Assumes full responsibility for assigned tasks;
- Make available information of public interest, complying with current legislation on privacy and data protection;
- Ensures the possibility for interested parties to lodge complaints and appeals with respect to their activities and undertakes to handle them;

The provisions defined and communicated by top management to all staff for the achievement of these objectives include:

- Compliance with the requirements of the standards for conformity assessment bodies;
- Full respect of the rules defined in the management system documents;
- Absolute independence of the top management and of the committee for safeguarding impartiality;
- The use of qualified personnel who work in absolute autonomy;
- Training and information of internal and external staff involved in certification activities;
- Avoiding creating situations that may give rise to grounds of appeal;
- Compliance with the planned programming for the implementation of certification and surveillance activities;
- Assessing the adequacy of the system and compliance with the benchmarks and objectives defined through the implementation of internal audits;
- Customer satisfaction evaluation regarding the certification service with appropriate tools.

Rho (MI), 24 marzo 2022

Sole Director

Dipl.-Ing. Feridoon Sergizzarea

