

INTELSINT was founded in **1989** as a provider of services and technical assistance for histology and pathology laboratories, where tumors and other important pathologies are diagnosed. After a few years, thanks to the skills and commitment of its founding partner and the goal of achieving greater success, the company also entered the field of design and production of instruments for the medical sector, specializing in histological sample preparation (pre-analytical phase). After identifying the real needs of the market, **INTELSINT** designed and manufactured one of the most important instruments in the field of pathology, the Tissue Processor. The first version was launched in **1998**. Over the course of its operations, the company has constantly improved, developing and producing increasingly innovative products (now in its fourth generation), until it has created a complete product line. Despite being a small Company, it has always been able to compete on the international market with the major industry leaders. Indeed, it was among the first to develop and produce an integrated stainer-slipper, the **AVR**. Customers are primarily Hospitals, Universities, and private laboratories. In Italy, it operates through direct sales. However, in the rest of the world, to offer a faster service that is more in tune with the economic and cultural context of its customers, management has chosen to establish a local Sales, Distribution, and Technical Assistance unit in each foreign market, managed by authorized dealers.

Operating according to the principles of **Quality**, for our Company means constantly working at all levels, to pursue continuous improvement in Business Processes, in the creation of products and services, responding to the Customer's requirements, of the **Regulation (EU) 2017/746 In Vitro Diagnostic Medical Devices "IVDR"** and which comply with **Legislative Decr. 81/08 Protection of Health and Safety in the workplace**. To comply with the new **"IVDR" Regulation** from **2023** we are registered in the **Eudamed Database** with all products. **INTELSINT** sets as primary objectives of its business:

- ➔ **compliance with applicable legal requirements** relating to their own aspects of products, safety and hygiene in the workplace;
- ➔ **Customer Satisfaction**, with reference to both the products and the services provided;
- ➔ **continuous improvement in the area of Safety and Quality**.

In **2007** we obtained certification from **TÜV Rheinland** in compliance with the **UNI EN ISO 9001:2000** standard, developed and improved over the years until obtaining the **UNI EN ISO 9001:2015** and **UNI CEI EN ISO 13485:2016** certifications in **2019**, in **2023** also the **UNI CEI EN ISO 13485:2021** Certification. Also in **2007**, the **RVG1** and **RVX1** Histology Processors were certified with the **ctUVus** brand; in **2013** the Certificate was updated with the subsequent models: **TP-300, FTP-300, ETP, EFTP**. In **2015** the **AUS1** Histological Slide Stainer was certified and in **2023** the **CVR** Coverslipper. Modifications to be made to some functions of the **ETP** and **EFTP** model processors are currently underway. Since **2018** we have been distributors for Italy of the **AS-410M DNS Automatic Microtome** (Dainippon Seiki), capable of carrying out all the processing phases of cutting blocks and applying them onto slides in a totally automatic way, for the subsequent coloring phase. The instrument is receiving a lot of interest, currently **7** have already been delivered. The Management does its utmost to offer its employees a safe, clean, non-stressful workplace, means of accident protection/prevention, regular checks with the Occupational Doctor and specific training.

The commitment to satisfying the Customer's needs focuses on:

- implement, obtain and maintain the Certifications by **TÜV Rheinland** of the **Quality Management System** in compliance with both **UNI EN ISO 9001:2015** and **UNI CEI EN ISO 13485:2021**.
- obtain and/or maintain the **ctUVus** branded Certifications relating to the products;
- systematic verification of compliance with the contractual terms, standards and objectives defined;
- the knowledge of the needs and expectations of our customers, through the care of direct communication with them and the monitoring of the quality of the products and services offered;
- the detection of the degree of Customer Satisfaction, by means of interviews, surveys, analysis of complaints or requests received;
- ensure the creation of innovative products in compliance with the **applicable safety requirements**;
- the constant offer of training courses and technical/commercial support, including online;
- aim at the success of our Customers / Distributors, because ours also depends on them.

INTELSINT pursues the continuous improvement of the effectiveness of its **S.G.Q.**, through:

- the achievement and maintenance of an adequate level of competence of **internal staff** and **Customers/Distributors**, based on the provision of training, on the development of skills and on the use of information technologies;
- the empowerment, involvement, motivation of all staff, stimulating discussions and proactive relationships, with periodic meetings and other activities; we are in fact convinced that it is essential that those who work with us are proud of what they do and why they do it;
- the pursuit of **continuous improvement** of the **Quality** of **products** and **services**, with the aim of pursuing technological excellence, combined with organizational simplicity to meet the needs of customers and reduce costs;
- the periodic review of the functioning of the **S.G.Q.** as a whole: Processes, documentation, achievement of Objectives, Corrective Actions, etc., through internal audits and / or by appointed bodies;
- a careful Risk Analysis carried out on all Company Processes.
- attentive listening to the customer, giving quick answers and professional support;
- the use of qualified suppliers and collaborators, who follow and respect the principles of our **S.G.Q.**

In order to achieve the objectives set out above, the Management undertakes to annually review this Declaration of the Quality Policy, illustrate it to all staff, keep it displayed on the bulletin board for consultation and insert it within the Management Document. All employees, in particular the Executives and Managers, have the task of ensuring that the principles indicated above are respected.