INTELSINT	QUALITY POLICY 2025	RR 530.01

INTELSINT was founded in **1989** by the founding member specialized in the technical assistance of scientific instruments for histology and pathological anatomy laboratories; during its activity it has constantly improved, developing and producing a range of increasingly innovative products, capable of competing on the international market with the great leaders in the sector. She specializes in the field of histological sample preparation (pre-analytical phase). To offer a faster service that is closer to the economic/cultural reality of the Customers, the Management has chosen to create a local Sales, Distribution and Technical Assistance unit in each foreign market.

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 new **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 5 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.

Villarbasse, **09.01.2025**

C.E.O. – Sergio Cometto