

Rosti Group Malaysia Achieves ISO 13485 For Medical Device Manufacture

ISO certification extends plastic moulding capabilities deeper into the medical sector



Singapore, Singapore Dec 12, 2021 ([Issuewire.com](https://www.issuewire.com)) - [Rosti Group](https://www.rostigroup.com), the European headquartered technology-led plastic moulding company, and contract manufacturer, has achieved ISO13485 in the Malaysia plant. Meeting the stringent requirements of the International Organization for Standards for a quality management system will expand on the Group's capabilities to deliver medical device prototypes 'from concept to reality' in 72 hours, and extend to full production of medical devices. The Rosti team overcame obstacles created by COVID to ensure the plant could attain certification in time to support medical device manufacturers.

The 5,000 m² facility is the fourth plant of the Rosti Group to attain ISO13485, following China, Romania in 2020, and Poland plant in 2021, and offers a diverse portfolio of capabilities to customers in the medical sectors with agile, total solutions from prototype to manufacture. In addition to injection moulding, printing, assembly, process development, tooling, and supply chain management, the plant possesses significant expertise in the production and validation of complex products. The Group was involved in the development and production of a 15 minute COVID saliva test. The global medical devices market size was valued at US\$ 447.63 Billion in 2019 and is expected to be worth around US\$ 671.49 billion by 2027

Rosti IMS Sdn Bhd Managing Director [Miller Brown](#) said, "The team effort in maintaining and continuously improving our systems to attain ISO13485 is a key characteristic of our facility at Rosti Malaysia. This helped us to develop new medical device projects with our customers and bring them to market. The way that the team worked together on this certification, considering the roadblocks that COVID-19 created, shows the dedication that the team has in improving Rosti Malaysia for the future," he said.

Rosti Malaysia, based in Johor, employs some 90 staff and plays a key role in the China +1 strategy of the Rosti Group. The Group operates 8 facilities worldwide, including 2 Digital Innovation Labs with a 3rd being added in the USA. Achieving ISO 13485 accreditation represents a significant investment from Rosti Malaysia, including a future investment into a controlled manufacturing area with medical specified injection moulding machines allowing the facility to operate at a medical level with full traceability.

Having ISO 13485 certified manufacturing facilities and capabilities to manufacture products and components for medical device, diagnostic (IVD), and pharmaceutical markets, provides the opportunity to develop extensive working relationships with current customers and opens opportunities to grow within the life sciences sector. Rosti Malaysia has already attained ISO9001, ISO14001, ISO45001 and is UL Certified.

About Rosti Group

Founded in 1944 with headquarters in Malmö, Sweden, the Group has 3,200 existing employees across 8 facilities in Europe and Asia and specialises in plastic moulding and outsourcing. Rosti is owned by the family-controlled investment company Nordstjernan. Please visit: <http://www.rosti.com>





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