Quality policy

Mediplast develops, manufactures and supplies medical devices and related products that meet customer, patient and other stakeholder requirements and expectations, with patient safety, product performance and quality as our highest priorities.

We establish, maintain and continually improve a documented Quality Management System in accordance with ISO 13485 and Regulation (EU) 2017/745 (MDR), as well as all other applicable national laws, regulations and relevant standards. Compliance with these requirements, and effective quality work, are a natural and integral part of every employee's daily activities so that quality and safety are always in mind.

Through our Quality Management System we:

- Ensure that applicable customer, regulatory and internal requirements are identified, understood and consistently fulfilled.
- Apply a risk-based approach throughout the entire lifecycle of our products, from design and development, through manufacturing and distribution, to post-market activities.
- Set, monitor and regularly review measurable quality objectives that support this policy, our strategic direction and our ambitions for high quality and service.

We are committed to effective post-market surveillance and vigilance, systematically collecting and analysing feedback, complaints and other post-market data, and implementing appropriate corrections, corrective actions and preventive actions to continuously improve our products, processes and services.

Top Management is accountable for the effectiveness of the Quality Management System, providing the necessary resources and a suitable work environment, and ensuring that responsibilities and authorities are defined, communicated and understood.

Through the commitment, knowledge and competence of all Mediplast employees, and by close collaboration with our customers and suppliers, we continuously strive to improve our products, maintain high levels of quality and service, and safeguard patient safety and regulatory compliance.

This Quality Policy is communicated, understood and applied at all relevant levels of Mediplast and is regularly reviewed to ensure that it remains appropriate, adequate and effective.

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Signatures:

Controlled Document Approved:	I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.
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