

# ME-Medical Enterprises

## Quality Policy

SRN: NL-MF-000019133

**ME-Medical Enterprises** designs, manufactures and distributes Synergo systems and disposable accessories.

The organization quality commitment is:

- To meet customer, statutory, and regulatory requirements and increase customer satisfaction through continual improvement of its manufacturing process, products, services and its Quality Management System.
- To maintain the effectiveness of the Quality Management System by means of internal audits, management reviews and corrective and preventive action procedures for any Quality Management System non-conformance.

**Medical Enterprises** quality values and beliefs are:

- Outstanding service to its customers
- Respect for its:
  - Customers
  - Suppliers
  - Shareholders
  - Employees
  - Community
- Creativity and teamwork in the workplace
- Honesty and integrity

**Medical Enterprises** has developed, documented, implemented, maintained and continually improves its Quality System to ensure compliance with US FDA 21 CFR Part 820 regulation, CE 93/42/EEC Directive concerning Medical Devices, European Medical Device Regulation EU (MDR) 2017/745 (EU 2023-607), EN ISO 13485:2016, Medical Device regulation 2002 (UK), Taiwan Food and Drug Administration (TFDA), The People's Republic of China Decrees No. 739, 47, 53, 64.

**Medical Enterprises** shall provide the personnel, facilities, equipment, systems, services, and training necessary to meet the requirement of our external and internal customers and shall satisfy the regulatory agencies requirements.

Dr. Avigdor Lev—CEO Medical Enterprises

24 Nov 2024

