

ZOT Engineering Ltd is responsible for and committed to the effective implementation of the hygiene policy in accordance with the requirements of ISO 13485 (Medical Devices). The hygiene policy is implemented and maintained to ensure we consistently produce hygienic products to specification, which are safe, comply with legislation and satisfy both customer and consumer needs.

The foundations of the Hygiene Policy are based on the following:

- Commitment to providing consistent, reliable products and services, ensuring all employees are trained, competent and actively involved in achieving defined and measurable objectives.
- Control and adherence to quality and hygiene procedures by employees.
- Management and monitoring of employee illness and disease.
- It is extremely important that employees report all cuts, skin rashes/conditions or contagious illnesses etc. to their supervisor/ manager prior to commencing any work on medical device product, identified by a BLUE Job card. Where a supervisor or manager has a concern about allowing any employee with a cut, skin rash/ condition or contagious illness etc. to work on medical device product they shall consult with the Top Management for clarification before allowing the employee to commence work on the product.
- Hand Hygiene: An alcohol hand rub, correctly applied to socially clean hands is an acceptable and very effective method of hand decontamination. The use of alcohol hand rub on socially clean hands is now the preferred method of hygienic hand hygiene.
- Hair Hygiene: When specified, during a manufacturing/ assembly operation, hair shall be covered by use of a hair net.
- The control of the manufacturing environment processes handling and protection of product to eliminate the risk of contamination by following good housekeeping practices.
- No eating, drinking or smoking in any production-manufacturing areas.
- Wearing of clean and adequate protective clothing, disposable overalls and gloves where appropriate. Overalls are to be laundered on a regular basis.
- Ensuring medical devices products are kept as clean as possible throughout the manufacturing, test, inspection and packaging processes. Specific hygiene/ cleaning instructions shall be documented in the quality plan and manufacturing procedures were appropriate.
- Implementation and monitoring of effective cleaning schedules and procedures in all manufacturing and packaging/dispatch areas. Hand hygiene must be followed prior to testing and packaging of medical device products prior to dispatch to customer.

The policy is implemented by ensuring that all employees are adequately trained in all aspects of company hygiene procedures and other requirements.

The effective implementation and improvement of our Management Systems is continuous and is maintained by a system of process audits, regularly reviewed and enhanced to maintain and continually improve our hygiene standards.

Signed: Johns Position: Chair

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