Core competencies

Technologies

Being a supplier of both components and complete solutions, we master a wide range of technologies.

Injection Molding
Our machinery includes injection molding machines with a clamping force ranging from 25 to 1250 metric tons.

Among the injection molding technologies we utilize multicomponent molding, air molding and insert molding.

Surface Treatment
Our surface treatment technologies include PTFE and hydrophilic spray and dip coating, PVD coating, plasma coating and hard coating.

Assembly and Finishing
We also perform other work on components such as manual or fully automated assembly, welding, decoration, embossing, glueing and chip cutting.

Our metal processing technologies include chip cutting and chipless processing for purposes such as production of guide wires, complete and ground needles, and cannulas.

Packing and Sterilization
We offer manual and fully automated packaging and labelling of components and complete devices to be delivered either sterile individually packed or bulk.

Quality and Regulatory

SP Medical's management system takes into account all the demands on and expectations faced by providers to the global medical devices and pharmaceuticals industries:

- We are certified to the ISO 9001, ISO 13485 and ISO 14001 standards.
- We have CE mark certification under the Medical Device Directive 93/42/EEC as amended by 2007/47/EEC.
- We are authorized to manufacture medicinal products under Eudralex Directive 2003/94/EC.
- We are an FDA-registered contract manufacturer.
- We comply with FDA Part 820 (QSR).
- We comply with the Global Harmonization Task Force Process Validation Guidance SG3/N99-10.
- We have MSA accreditation.
- We build and maintain our cleanroom environments in accordance with ISO 14644 and ISO 14698.

Quality Activity Plan

Our project management model includes a Quality Activity Plan (QAP) that defines requirements for the relevant product.

Our QAP complies with the requirements set out in EU-GMP/GLD/GDP, FDA Part 820 (QSR) and the Medical Device Directive 93/42/EEC as amended by 2007/47/EEC.

This means that we prepare documentation in the form of Design History File (DHF), Device Master Record (DMR) and Device History Record (DHR).

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