

SP Medical A/S: A Brief Introduction

SP Medical's mission is to develop, manufacture and provide plastics and surface solutions to the global medical devices and pharmaceutical industries. In addition to customized solutions, standardized products and own-brand products, we offer systems and logistics solutions.

SP Medical has more than 50 years of experience in working with plastics. Our capabilities cover a large part of the value chain: from design and development to production and distribution of complete devices, including the necessary documentation for regulatory approval of the products.

Our clients include some of the world's largest manufacturers of diagnostics equipment, medical devices and pharmaceutical products. We also have smaller biotech and medical devices companies as our partners.

Our production and processes are certified to a number of standards. We have FDA approval and are subject to extensive documentation requirements for the production of pharmaceutical equipment.

SP Medical has state-of-the-art production facilities in Denmark and Poland.

Core products



Medical Devices

SP Medical manufactures medical devices using injection molding as its primary technology.

The company makes individual components, processes semi-manufactured plastic components and manufactures complete devices.

Guide Wires

SP Medical develops and manufactures CE marked guide wires and packing components both as private label products and under its own brand.

These products are aimed at medical fields such as angiography, cardiology, urology, radiology and with a focus on minimally invasive procedures.

Coatings

SP Medical surface treats medical devices with performance improving coatings such as PTFE and hydrophilic coatings. We can spray coat or dip coat pieces with or without markings.

Pharma

SP Medical has developed a production concept employing plastics technology to manufacture tablets with an active drug content (medicines). The tablets are injection molded with a coating and one or more matrices in a single process, i.e. a multicomponent molding process.



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, gluing 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 labeling of components and complete devices, as well as sterilization.

Quality

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).
- 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/ISO 14698.

Quality Activity Plan

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

Our QAP takes into account the documentation requirements set out in EUGMP, FDA Part 820 (QSR) and the Medical Device Directive (93/42/EEC).

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

