

Biomedical



Project Detail

Biomedical products and solutions demand precision and quality. One German company, a leader in the field of automated pathology diagnostics, had very specific requirements when looking to source consumables for their next-generation laboratory platform. Simply put, they required exceptional quality, absolute precision and, most importantly, traceability across manufacturing runs of up to one million pieces per annum.

Precise geometry, and optical clarity validated to the agreed specification, are critical to system performance, and ongoing compliance with rigorous Biomedical manufacturing approvals, including the stringent US Federal Drugs Administration.

Solution

The Biomedical industry is driven by innovation. In order to keep up with the increasing complexity of diagnostic platforms and shortening development cycles, the Biomedical companies need relationships with trusted suppliers who offer a complete solution for manufacture and validation, not inflexible suppliers tied to a single manufacturing methodology. Hosico met this requirement, and was also able to provide the client flexibility in design and peace of mind that the delivered product would be to the highest possible quality.

Hosico's solution of custom robotics, combined with an automated vision inspection system, provide repeatable manufacturing of an optically-critical plastic consumable with a less than negligible rate in a volume of over one million parts per annum. Real-time statistical sampling and reporting detect any trend away from the required specification and allow fine-tuning of the process for optimal throughput, yield, and quality.

Unlike other industries, in the Biomedical industry, where patient outcomes depend on accurate results, it is important that every component of a diagnostic system be validated, and indeed traceable back to the point of manufacture. Hosico has integrated batch identification to the final component inspection process to complete the chain of responsibility.

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Manufacturing and engineering challenges that Hosico overcame in the delivery of this solution included:

- a need for an optically clear polymer;
- maintenance of polymer densities and critical geometries during moulding to prevent optical distortion;
- 100% quantitative optical inspection while maintaining throughput;
- component traceability at small batch level in high volume production.

The core manufacturing methodology and raw material used in this manufacturing assignment is:

- polymer, chosen for its dimensional stability and superior optical qualities;
- moulding machine;
- robotic handling platform;
- machine vision inspection system.

Outcome

Hosico moulds and individually inspects over one million components per annum, with a less than negligible reject rate. These components are a critical consumable in a system trusted to accurately detect cancer in patients around the world.