

Company: Customer 1 Customer Duration: 7-Years

Service: Equipment Systems Integration
Sector: Medical Device; 1000 employees

Project Overview: Unique Device Identification (UDI) and Lot Integrity (LI) system's on a total of thirty seven medical device production and packaging lines at their production facility.

Strategic Targets:

Develop an 'UDI and LI System' comprising;

- Unique Device Identification for all product produced
- Ensure the integrity of all Lot Data across all cells in the production line
- Line clearance/purges and lot management control systems
- Quality control and verification systems

Outcomes Achieved:

The lines within Customer 1's facility consist of automated assembly, sterilisation and packaging.

'The SL Controls solution is responsible for full data lot management of the lines. It controls the transfer of all lot data to the equipment, identification and verification systems.'

Our system;

Manages the interactions with the user to create the line clearance/purges interlocks and product changeover controls for lot management. It controls all printer details and vision verification systems, and lot parameters

Logs all lot details of the product

Is fully integrated to the site ERP and both ends of production and 21CFR11 compliant

SL Controls provided a full GAMP5 validation package for all systems installed on the site