DTR Medical is an award-winning manufacturer of single-use surgical devices.

Based in the UK, and trading since 2005, the company has developed a range of innovative devices for use across healthcare – including general surgery, gynaecology, neurosurgery and ophthalmology.

New regulation triggers business change

As leaders in their field, DTR Medical wants to be ahead when it comes to complying with global and local regulations:

- In the US, the Food and Drug Administration (FDA) requires all medical devices to carry a Unique Device Identifier (UDI) – for example a GS1 barcode. All devices must also be registered with the FDA’s Global Unique Device Identification Database (GUDID).
- In the UK, the Department of Health published the eProcurement strategy, which mandates the use of GS1 standards for all products and services supplied to the NHS.
- In Europe, there is likely to be further legislation in this area, including similar regulations being introduced for the unique identification of medical devices.

Meeting these regulations is potentially a time-consuming and admin-intensive process. DTR Medical looked for a simple way to automate UDI compliance.

A solution to meet current and future business needs

DTR Medical needed a solution to meet their current and future business needs. They met with GS1 UK accredited partner, Kodit, who introduced their UDI compliance solution.

The software provides a ready-to-go cloud-based UDI platform. Simple to use, it allows DTR Medical to create and manage GS1 compliant labelling to FDA and NHS standards while, at the same time, seamlessly connecting their product information to a data pool.

“Delivering the twin benefits of regulatory compliance and business process efficiency from one project is an unusual and very welcome development for our organisation.”

Andrew Davidson, Managing Director, DTR Medical
The platform is integrated with Zebra’s – also a GS1 UK accredited partner – ZT400 label printer to produce 2D barcodes in high volume on label materials, which is designed for use in medical environments.

**Slicker business process**

Kodit helped DTR Medical reduce its library of label templates from close to 100 down to five.

Now when DTR Medical start a production run, a job pack is created, which includes labels. The labels are cross-checked and need to be signed-off by designated team members to ensure that the correct data is produced. When the job is released from production, labels are printed for the boxes that transport the devices and the individual pouches for each device.

UDI label data created for each device is now automatically retained and secured by the Kodit UDI solution and, as needed, data is exchanged via data pools with compliance databases.

Even in a small company, the data that UDI requires comes from several sources and bringing it all together is time consuming. Kodit guided DTR Medical through this process to make them ‘data ready’.

**Simpler and less expensive barcode labels**

Like many SMEs, DTR Medical have been running the same label software for years. The Kodit system not only enabled them to become UDI compliant, but also overhauled their label creation – using Kodit’s cloud based software. They were also able to convert their expensive traceability barcode labels to a simpler and less expensive design.

**New business opportunities**

There is a move globally towards device labelling and DTR Medical now has a system in place that can easily create templates which comply with the requirements of different countries. It has identified several new business opportunities as a result of its new UDI capabilities. Furthermore, being data ready, ahead of the expected roll-out of the FDA and NHS requirements, reinforces DTR Medical’s positioning as a pioneer in their field.

DTR Medical can show they have a system in place to help NHS customers meet regulations and achieve savings – by better planning and managing their inventory – using GS1 barcodes.

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**Kodit UDI**

Kodit is a GS1 accredited partner who provide a comprehensive unique device identification (UDI) solution for organisations that manufacture, supply or utilise medical devices.

**Zebra Technologies**

Zebra is a GS1 UK accredited partner. Their ZT400 printers provide quick, high-quality label printing – at up to 600dpi – in a highly reliable device that can print barcodes on a range of label materials that are proven for use in clinical environments.

**Data pool**

A data pool allows you to enter your product information into a single system, which can then be shared with trading partners and submitted to regulatory databases (such as GUDID) globally. GS1 UK’s data pool is called TrueSource.