



Medical device marking, streamlined and secure

BarTender® is at the heart of FDA-compliant UDI installations around the world, providing legendary ease of deployment and acclaimed technical support.

Manufacturing in the medical device industry is ramping up to levels not seen since before the global recession of the late 2000s. But this production boom is complicated by the implementation of new, stringent UDI rules. Because patient safety is at the core of UDI regulation, there is no room for compromise.

Medical device manufacturers require labeling solutions that are secure, proven and reliable, and at the same time scalable and adaptable to evolving business practices. The technology deployed to help meet UDI protocols must provide complete, seamless, immediate integration with existing systems and workflows.

BarTender: The heart of your UDI compliance labeling solution

BarTender® is a trusted component of FDA-compliant UDI installations around the world, delivering secure, auditable barcode and RFID labeling to help maintain regulatory compliance. Seamless integration with ERP systems like Oracle and SAP enables automation

at the enterprise level, providing increased labeling accuracy while also improving efficiencies throughout the supply chain. BarTender's centralized control connects your business data with a wide variety of printers—whether you have one printer at a single plant or thousands of printers at facilities around the world.

Built-in security and compliance

Built to help meet the security demands of UDI, BarTender provides full audit trail capabilities throughout the entire labeling process. Printer-based licensing and layers of customizable settings add broad protections to the printing environment, with security features ranging from basic print-only settings to complex role-based permissions with label format encryption.

Simple, intuitive templates offer the agility to rapidly perform and deploy design, data and format changes, with support for meeting evolving interoperability standards through HL7-based UDID communication.

BarTender and UDI

Medical device manufacturers choose BarTender for its unparalleled security and serialization capabilities. BarTender is scalable to any system requirement and adaptable to the entire spectrum of AIDC technologies.

- Centralized control to lock down any part of a template. Customize access by product, container, geography, business unit, operator, or other parameters, based on business needs.
- Layered security features, ranging from basic print-only settings to complex role-based permissions with label format encryption.
- Share incrementing serial numbers with UDI across your network. Flexibility for serialization per-page or per-job, or by data source or database field change.
- A seamless connection between your ERP system and your label printer, whether used with one printer at a single plant or thousands of printers at facilities around the world.





BarTender for UDI compliance labeling: Dependable. Scalable. Adaptable.

RFID

Since RFID can be read without line of sight, selecting this Auto ID technology for UDI can also provide powerful supply chain efficiencies for the medical device manufacturer, providing tracking support throughout production, warehousing and shipping. Tags can be sewn into a textile device or included in a carton, and an RFID-embedded implantable device offers unique post-market surveillance capabilities.

With BarTender, the design and coding of RFID tags is as simple as creating a standard product label and barcode. BarTender includes built-in RFID antenna coding, and is fully compliant with EPCglobal's Gen 2 standard (ISO 18000-6C), and supports a comprehensive list of RFID tags and encodings.

Seagull Scientific can help you meet UDI compliance labeling regulations, wherever you manufacture or sell medical devices. To learn more, visit the BarTender medical devices industry web page, featuring interactive guides to Auto ID and marking technologies.



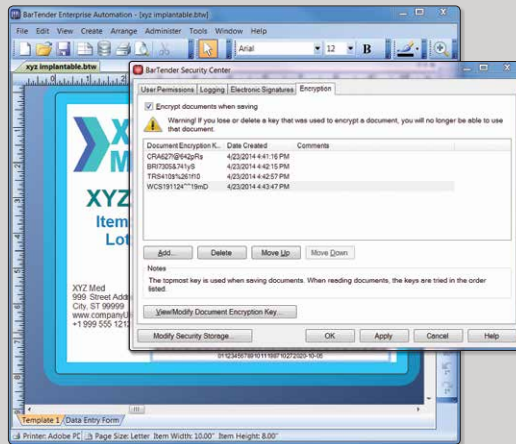
www.SeagullScientific.com/label-software/medical-devices.aspx

BarTender and regulatory compliance

BarTender is successfully deployed in systems validated by the US FDA and European Commission. BarTender's Security Center, included in Automation and Enterprise Automation editions, includes powerful capabilities that can enable compliance with the most stringent regulatory requirement.

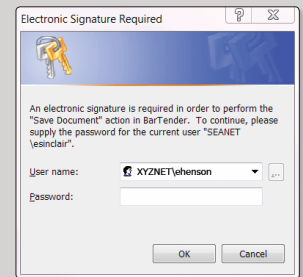
Security

BarTender offers a complete spectrum of customizable security options, ranging from simple Print-Only mode, to complex role-based permissions: Control access to label design and modification, database setup, document saving, printing and more from a central location onsite—or at a facility on the other side of the world. Label format encryption can be applied to any of the security levels, providing an additional layer of protection against unauthorized use.



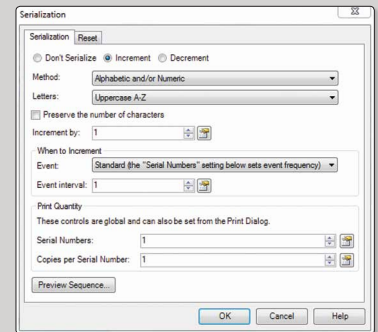
Electronic signatures and data logging

BarTender's electronic signature feature and comprehensive data logging capabilities combine to bring full audit trail accountability to the entire labeling process, enabling compliance with high security standards, including the CFR 21 Part 11 guidelines.



Serialization

BarTender supports the incrementing of serial numbers at a single printer or at printers across a network, and can share data sources among all documents through the system database. Serialize per-page, per-job, when changes occur in a data source or database field, or when the time or date changes.



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