FDA UDI Compliant Label Substrates for Medical Device Market

MDT Staff

FLEXcon has announced the launch of FLEXcon MedFLEX, a line of label substrates that meets all performance criteria required by the Food and Drug Administration's (FDA) proposed unique device identifier (UDI) rule. The legislation will require Class II and III medical devices distributed in the U.S. to carry a unique numeric or alphanumeric code with an identifier specific to each device or model as well as an identifier with current production information. The FLEXcon MedFLEX line is UL-certified in accordance with UL/IEC 60601-1 3rd edition marketing durability rub tests and all products are available for immediate UL adoption.

In addition to the usage of materials that comply with UL/IEC 60601-1 3rd edition marking durability rub tests, and potentially UL-recognized materials, the FDA UDI rule will also require specific information and barcodes on all product labels. Manufacturers will also need to maintain the data gathered for track and trace purposes. FLEXcon MedFLEX products not only meet these requirements, they utilize FLEXcon's high-performance acrylic adhesives and their best thermal transfer printable topcoats. Three of the products are UL-recognized with inks and ribbons and all products are immediately adoptable into converters' UL files.

For more information, visit www.FLEXcon.com [1].

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[1] http://www.flexcon.com/