



Unique Device Identification (UDI) Labeling Supply Selection Guide

The Food and Drug Administration (FDA) requires that medical devices that can be used more than once and all levels of packaging are labeled with a Unique Device Identifier (UDI). The UDI system was established as a system to identify medical devices throughout their use, making the reliability and readability of labels key to complying with this regulation.

KEY APPLICATIONS

- Medical devices
- Medical device packaging



Medical Devices

UDI device labels must meet UL standards and be able to withstand extreme environments such as sterilization and harsh hospital cleaning agents. In addition, UDI labeling requires excellent print quality to print small fonts, regulatory icons, and the 2D barcode containing all the information. Labels may also need to be flexible for devices with curved or uneven surfaces. UDI labels must remain machine-readable and readable by humans as long as the device is in use.

Top recommended products for medical device labeling:

Product Name	Material	Adhesive	Key Attributes	Durability
Z-Ultimate 4000T	Thermal transfer gloss polyester	Thermal transfer gloss polyester	Also available in silver and clear	Unparalleled resistance to moisture, abrasion, and weak to moderate chemicals (isopropyl, alcohol, bleach, etc.); UL/cUL and CSA approved; Sterilization resistance to steam autoclave, gamma radiation, ethylene oxide
Z-Xtreme 4000T	Thermal transfer matte polyester labels	High-performance acrylic	Also available in silver	Good resistance to scratches, smearing, moisture and weak to moderate chemicals (isopropyl, alcohol, bleach, etc.); UL/cUL and CSA approved; Sterilization resistance to steam autoclave, gamma radiation, ethylene oxide
Z-Xtreme 5000T	Thermal transfer matte polyester	Permanent acrylic	Temperature exposure up to 300 degrees	Excellent resistance to extreme chemicals, as well as moisture and abrasion; UL/cUL approved

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Product Name	Material	Adhesive	Key Attributes	Durability
PolyPro 3000T	Thermal transfer matte polyester	High-tack permanent acrylic	High print quality and some flexibility for labeling curved surfaces, meets FDA 175.105 for indirect food contact requirements	Resistant to scratches, smearing, moisture and weak to moderate chemicals
PolyPro 4000T	Thermal transfer matte Kimdura polypropylene	Permanent acrylic	Meets FDA 175.105 for indirect food contact requirements	Good resistance to moisture and weak to moderate chemicals (isopropyl, alcohol, bleach, etc.); sterilization resistance to steam autoclave, gamma radiation, ethylene oxide
PolyPro 4000T High Tack	Thermal transfer matte Kimdura polypropylene	High-tack permanent acrylic	Meets FDA 175.105 for indirect food contact requirements	Good resistance to moisture and weak to moderate chemicals



Medical Device Packaging

UDI labeling doesn't only apply to medical devices themselves. Packaging and shipping cartons must also have labels that contain the UDI; however, the label for packaging would not have to have the same damage-resistant properties as the label for the medical device itself.

Top recommended products for medical device packaging labeling:

Product Name	Material	Adhesive	Key Attributes	Durability
Z-Select 4000T	Paper	Permanent acrylic adhesive	Specially coated for high print quality; can be used on most packaging materials and across a wide temperature range	Limited resistance to moisture, abrasion and chemicals
PolyO 4000T	Thermal transfer highly flexible corona-treated polyolefin	All-temp permanent acrylic adhesive	Meets FDA 175.105 for indirect food contact requirements, excellent conformability to tight diameters	Excellent resistance to oil, alcohol, dirt, blood, and water; some smear/scratch and chemical resistance