

## Application Guide

# Medical Device UDI Labeling

### Industries:

Class 1, 2 and 3 medical devices.

### Products:

Thermal transfer printable labels:

XF-455 and XF-583

Laser markable labels:

XF-670 and XF-672

### Applications:

UDI approved labels for multi-cycle sterilization autoclave and disinfectant washer trays, baskets, etc.

### UDI Compliance:

Tested to UL/IEC 60601-1/61010-1  
complies with Title21- Food and Drug  
chapter 1, subchapter H, class II  
multi-use medical device  
coating requirement.

### Customer Benefits:

- High durability, temperature and chemical resistances for long term survival in ultra-harsh environments.
- High temperature and high strength Pressure sensitive adhesives (PSAs) for adhering to either high or low surface energy (LSE) materials.
- Halogen free, low out gassing REACH and RoHS compliant.
- Laser Markable Labels can be ablated by low power CO<sub>2</sub>, fiber, YAG, UV and vanadate lasers.



### Industry Needs

Public safety is a key concern for medical device manufacturers and service labs. Not only do medical devices need to perform accurately and have long lives, but also need to not further complicate the medical ailment they're being used to treat. In addition, the use of all medical devices now needs to be carefully recorded so future diagnoses can rely on the data to better understand the patient's medical history.

The Food & Drug Administration (FDA) will soon require all medical device manufacturers to label their devices with UDI "Unique Device Identifier" labels. The medical devices are broken into three classes based on the level of control necessary to assure their safety and effectiveness, they are Class I (low risk medical materials), class II (support health and well being) and class III (support or sustain life—highest risk). The UDI initiative will also require all manufacturers to verify the label's durability and readability through the life of their devices.

The UDI label can include human readable text, automated information formats (barcodes) and/or RFID information. The data collected will be entered into a new Global Unique Device Identification Database, (GUDID) for regulators and physicians to review issues of safety and compliance, issue recalls, etc

***"UDI initiative requires manufacturers to verify the label's durability and readability through the life of their device"***

### Polyonics Solutions

Polygonics has developed two families of label materials that meet the performance requirements of the FDA Unique Identification (UDI) initiative for class II and class III medical devices. The materials fully comply and have been tested to the UL/IEC 60601-1 and UL/IEC 61010-1 for coating durability and as such are fully FDA approved.

The REACH and RoHS compliant materials include polyimide (PI) or PET films, renowned for their chemical resistance and dimensional stability in high temperature and harsh environments. Polygonics coats the films with durable, cross linked polymer coatings that allow either thermal transfer printing with a wide range of inks or ablation and cutting by YAG, fiber, CO<sub>2</sub>, vanadate and UV lasers. Both methods produce high contrast linear and 2D bar codes and alpha numeric characters. The label materials include high temperature PSAs and liners for die cutting and application.



*For more information or to receive samples for evaluation, please contact:*

**info@polyonics.com or 603.352.1415**

| Product | Film/face                          | Adhesive                            | Total Thickness | Applications   | Description   |
|---------|------------------------------------|-------------------------------------|-----------------|--|---|
| XF-455  | 50 µm<br>Gloss white polyester     | 25 µm<br>low surface energy acrylic | 76 µm           | Asset tracking, UDI, automotive, low surface energy plastics.  | <b>Thermal transfer printable.</b><br>Chemically resistant polyester, REACH, RoHS and UL/IEC 60601 <sup>2</sup> /61010 <sup>1</sup> compliant.<br>Temperature range: -40° to 148°C  |
| XF-583  | 25 µm<br>semi-gloss polyimide      | 25 µm<br>solvent acrylic            | 64 µm           | High temperature tracking, UDI applications including autoclave.   | <b>Thermal transfer printable.</b><br>High temperature, durable label material. Extreme chemical resistance, REACH, RoHS and UL/IEC 60601 <sup>2</sup> /61010 <sup>1</sup> compliant.<br>Temperature range: 100 hrs at 125°C<br>5 min at 260°C / 90 sec at 300°C              |
| XF-670  | 25µm<br>black antistatic polyimide | 25µm<br>low surface energy acrylic  | 66 µm           | Harsh environment tracking, UDI, automotive under-the-hood, aerospace, IUID, LSE materials, plastics, etc.             | <b>Laser markable.</b> High Temperature, harsh chemical resistance ESD black top coat. Low outgassing, halogen free, REACH, RoHS and UL/IEC 60601 <sup>2</sup> /61010 <sup>1</sup> compliant.<br>Min. application temperature: 32°F (0°C)<br>Temperature range: -70° to 260°C |
| XF-672  | 25µm<br>TrueWhite™ polyimide       | 25µm<br>low surface energy acrylic  | 66 µm           | Harsh environment tracking, UDI, automotive under-the-hood, aerospace, IUID, LSE materials, plastics, etc.<br>Low Soot | <b>Laser markable.</b> Abrasion Resistant white top coat. Low outgassing, halogen free, REACH, RoHS and UL/IEC 60601 <sup>2</sup> /61010 <sup>1</sup> compliant.<br>Min. application temperature: 32°F (0°C)<br>Temperature range: -70° to 260°C                              |

<sup>1</sup> 30 sec double rubs with 70 isopropyl alcohol

<sup>2</sup> 15 sec double rubs with distilled water + 15 sec double rubs with methylated sprits + 15 sec double rubs with 70 isopropyl alcohol

## POLYONICS AT A GLANCE

Polyonics manufactures high performance polymeric materials for harsh environments. These include printable and laser markable label materials, single and double coated engineered tapes and flexible substrates with highly reflective and printable top coats. Polyonics materials are used by OEMS and converters worldwide. The ultra-thin polyimide, polyester and aluminum materials are designed expressly for high temperatures and harsh environments plus provide flame retardant and static dissipative performances for electronics, automobile, aerospace and medical components.



Autoclave photo courtesy SciCan

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