

Polyonics R&D Test Report: Medical Device (UDI) Label Durability Test Results for Laser Markable Label Materials

Objective: Determine compliance of the Polyonics laser markable label materials (LML) to the Title 21-Food and Drugs chapter 1, subchapter H medical device UDI labeling requirements.

Background: The FDA requires all medical OEMs to identify and track their products through the manufacture and life of the products via a unique device identifier (UDI). The FDA has closely defined the UDI procedure and has included coating durability tests for any label materials used in the ID and tracking process. The durability test procedures are defined by the UL/IEC 60601-1 (for new and legacy medical devices) and 61010-1 (for laboratory equipment) requirements.

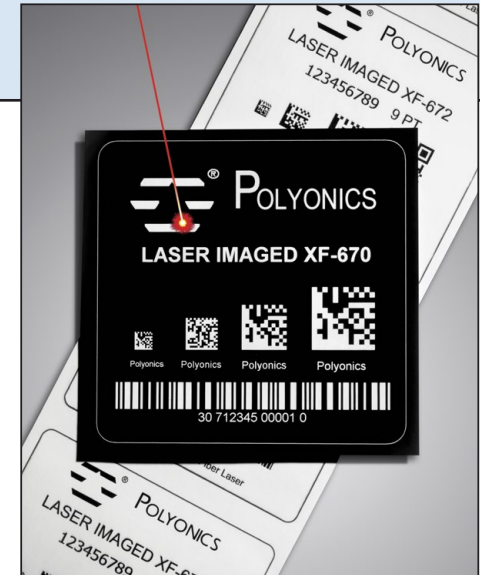
TEST METHODS:

UL/IEC 60601, section 7.1.3B (third edition) New and legacy medical devices

- Labels are rubbed by hand, without undue pressure, first for 15 seconds with a cloth rag soaked with distilled water, then for 15 seconds with a cloth rag soaked with methylated spirit (95% ethanol 5% methanol), then for 15 seconds with a cloth rag soaked with isopropyl alcohol.
- The markings on the labels shall be clearly legible and adhesive labels shall not have worked loose or become curled at the edges.

UL/IEC 61010-1, section 5.3 (third edition); Laboratory equipment

- The labels are rubbed by hand, without undue pressure, for 30 seconds with a cloth soaked with each specified cleaning agent (or, if not specified, with 70% IPA).
- The markings on the labels shall be clearly legible and adhesive labels shall not have worked loose or become curled at the edges.



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UL/IEC Test Results

TEST	XF-537	XF-538	XF-539	XF-670	XF-671	XF-672	XF-684
UL/IEC 61010-1	Pass	Pass	Pass	Pass	Pass	Pass	Pass
UL/IEC 60601-1	Pass	Pass	Pass	Pass	—	Pass	Pass

UDI Class II Autoclave and Detergent Wash Station Results

PROPERTIES	TEST METHODS	RESULTS	
Temperature Rating:	Long Term	100 hours at 302°F (125°C)	
	Operating	5 minutes -67F (-55C) to 500F (260C)	
	Short Term	90 seconds at 572°F (300°C)	
UDI Performance¹	Sterilization	>3300 Cycles at 134°C/3.5 minutes	
	Wash/Disinfection	>1000 cycles	
		HIP Detergent Wash	50°C
		Disinfection	90°C/10 Minutes
Coating Durability	ASTM D4752-10	IPA	MEK
		>100 Double rubs	>12 Double rubs
	Abrasion (GMW 3208)	>100 cycles	
Out Gassing¹	ASTM E595	TML ≤ 1.02%, CVCM ≤ 0.03%, WVR ≤ 0.54%	

¹ Third Party Testing

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