

### Are Your Food Scanner X-ray Curtains Approved for Food Contact?

Maintaining FDA compliance in the food industry has always been crucial. With the recent increase in focus on sanitation procedures, it is important to review the elements of the regulations we follow.

The term “FDA approved” is often misused to describe food-safe materials that have not been tested directly by the FDA. The correct terminology for x-ray curtains and similar food handling components is FDA Compliant.

The “FDA is responsible for protecting public health by regulating human drugs and biologics, animal drugs, medical devices, tobacco products, food (including animal food), cosmetics, and electronic products that emit radiation.” However, only select products undergo premarket approval by the FDA.<sup>i</sup>

#### Are Your X-Ray Curtains Properly Certified ?

Ensure compliance with regulations by asking your supplier for these two forms:

- 1) Certificate of Conformance with the ROHS ‘lead-free’ Directive 2011/65/EU
- 2) Certificate of Compliance with US FDA Article 177 or EC Directive 1935/2004 for Food Contact Articles

Food Manufacturers look at two primary factors when determining whether an x-ray curtain is safe to use in their food manufacturing facilities.

#### 1. Are the Curtains on the X-Ray Scanning Machine Compliant with the ROHS ‘Lead-Free’ Directive?

The word “lead-free” is commonly used in reference to plumbing fixtures, paint, solder, ceramics, and food additives. Lead-free can also apply to food inspection equipment. The FDA requires that food manufactures evaluate food packaging material in order to uncover defects like loose particles, unpleasant odors, **absorption of lead from equipment**, and more.<sup>ii</sup>

With food x-ray scanners, lead-free most often refers to the material used to ‘block’ or attenuate x-rays in the curtain shields which cover the conveyor tunnels. A lead-free curtain would usually contain heavy metals, which could include tungsten, tin, antimony, bismuth and barium.

When considering the x-ray curtains used on food inspection equipment, the Restriction of Hazardous Substances (ROHS) Directive addresses ‘lead-free’ compliance limiting the lead content to 0.1% by weight. XrayCurtains.com has been manufacturing lead-free curtains since 2004 and provides a Declaration of Conformity with the ROHS Directive for lead-free curtain shields.

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# Lead Free Shields

X-ray  
Curtains

## 2. Are the X-ray Curtains “Food Contact Compliant” ?

Most x-ray curtains are made from polymers for flexibility. When in the food inspection x-ray curtains will be in direct contact with food, the materials used must be compliant with the FDA Code of Federal Regulations addressed in 21 CFR Part 177- Indirect Food Additives: Polymers under Subpart C— Substances for Use Only as Components of Articles Intended for Repeated Use.<sup>iii</sup>

XrayCurtains.com offers Food Contact x-ray curtain shields made from rubber. This requires compliance with article 177.2600 “Rubber articles intended for repeated use”. In order to certify compliance, the material must meet rigorous testing standards for contact with both aqueous and fatty foods.

Our food contact x-ray curtain shields have been tested at certified laboratories to allow us to issue Certificates of Compliance with US FDA and European regulations for direct food contact.

**For answers to food compliance questions for your facility, reach out to us at (832) 519-8787 or at [sales@leadfreeshields.com](mailto:sales@leadfreeshields.com)**

Find us online at [www.xraycurtains.com/food-scanner](http://www.xraycurtains.com/food-scanner)

## Lead Free Shields

X-ray Curtains

### Declaration of Conformity

*Restriction of Hazardous Substances (ROHS) Directive*

Directive 2011/65/EU of the European Parliament and the Council of 8 June 2011


This declaration confirms that the products listed herein are in compliance with Directive 2011/65/EU for Restrictions of Hazardous Substances (RoHS) at the time of delivery and that the maximum concentration values tolerated by weight for lead, hexavalent chromium, cadmium, mercury, polybrominated biphenyls and polybrominated diphenylethers are in compliance. This statement is based on information provided by our suppliers and is accurate to the best of our knowledge.

This Declaration of Compliance is effective for the following products:

UltraLight Curtains	FDA/IEC Compliant	Lead-Free Vinyl	Lead-Free Vinyl
XRC101RNB125	XRC115KB125	XRC135VNB125	XRC135VBK500
XRC101PNB125	XRC115KB250	XRC135VSB125	XRC135VSB500
XRC101UBK125	XRC116RBL125	XRC135VBK250	XRC135VSB001
XRC101UBK250	XRC116RBL250	XRC135VGR250	XRC135VSB002
XRC101UBK350	XRC121KB125	XRC135VSB250	XRC135VSB003
	XRC121KB250	XRC135VSB350	XRC135VSB004
	XRC122RBL125		
	XRC122RBL250		

Please contact us to answer any questions regarding these products or other products offered for sale by Lead Free Shields or XrayCurtains.com.

Confirmed as of this 1<sup>st</sup> day of January 2020  
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## Lead Free Shields

X-ray Curtains

### Declaration of Conformity

*for technical products made of rubber that come in contact with food*

The products described herein meet the US Food and Drug Administration requirements for Direct Food Contact through compliance with the following FDA administrative regulations.

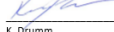
Article 21 CFR 177.2600 for “Rubber articles intended for repeated use”

The materials described below are declared to be compliant as a food contact substance, specifically as an indirect food additive, per subpart 177.

Material	Description
XRC116-RBL125	FDA Compliant Food Contact Xray Curtains, Lead Free 0.125mm LE
XRC116-RBL250	FDA Compliant Food Contact Xray Curtains, Lead Free 0.250mm LE

Compliance was established by the National Food Lab and confirmed under a report issued on July 9, 2019 specific to tests in accordance with 21 CFR 177.2600 parts (e) and (f).

Please contact us to answer any questions regarding these products or other products offered for sale by Lead Free Shields or XrayCurtains.com.

  
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<sup>i</sup> <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved>

<sup>ii</sup> <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/miscellaneous-food-products-vol2>

<sup>iii</sup> <https://www.law.cornell.edu/cfr/text/21/part-177>