

Aramus™ Single-Use Bag and Assemblies¹: Certificate of Compliance²

Country of Origin: USA

Compliance Statements:

BIOLOGICAL REACTIVITY	STANDARD	STATEMENT
Biological Reactivity – <i>In Vitro</i>	USP <87>	Representative Aramus single-use bags and assemblies have been tested and meet these biological reactivity standards.
Biological Reactivity – <i>In Vivo</i>	USP <88>	
Endotoxin	USP Class VI	
Hemolysis	USP <85> and EP 2.6.14	
PARTICULATES		
Particulate matter in single-use components and assemblies	USP <788> and EP 2.9.19	Representative Aramus single-use bags and assemblies have been tested and meet the particulate requirements established in USP <788> and EP2.9.19.
STERILIZATION		
Qualify the sterilization of healthcare products by irradiation	ANSI/AAMI/ISO 11137-2, Radiation dose Method VDmax for minimum dose of 25 kGy to provide Sterility Assurance Level (SAL) of 10 ⁻⁶	Representative Aramus single-use bags and assemblies have been validated for sterility after exposure to gamma irradiation.
FOOD CONTACT		
Indirect Food Additives – Polymers	21 CFR 177	Fluoropolymer resin used to manufacture the film and fitment comply with the requirements set forth in FDA specification 21 CFR.177.1550.
ANIMAL ORIGIN		
TSE/BSE Statement	TSE/BSE	Aramus single-use bags meet TSE/BSE requirements.
EXTRACTABLES		
Physiochemical Container Test	USP <661>	Representative Aramus single-use bags have been tested and meet the requirements established in USP <661>.
ENVIRONMENTAL IMPACT		
RoHS REACH	Directive 2011/65/EU Regulation EC/1907/2006 Directive 2006/122/EC3	Entegris has a long history of environmental compliance in countries of operation / distribution. Entegris actively reviews products for compliance and conformance with government and customer requirements affecting raw materials / substances that may be used in manufacturing processes.

Manufacturing Environment: Quality & EHS Management Systems: Certified to ISO 9001:2008 and ISO 14001:2004

General: The information in this overview is provided for the purpose of communicating regulatory compliance for Aramus single-use bags and assemblies as shipped from an Entegris location. Entegris relies on the compliance testing and analysis performed by our raw material suppliers as the foundation for the listed regulatory statements, and Entegris makes no representation or warranty with regard to any such testing and analysis. Entegris makes no warranty, express, implied or statutory, with regard to the product(s) described in this overview, including, without limitation, the implied warranties of merchantability and fitness for a particular purpose. Ultimately, the customers must determine that use of this product is safe, lawful and technically suited for their intended application and purpose, and Entegris assumes no liability for any loss or injury which may result from the use of the information contained in this overview.

Endnotes:

1. Aramus single-use bag assemblies include the Aramus bag and welded fitment along with components that have been connected to the bag such as tubing and fittings. These are components that come into contact with the process/product. In the case of components not manufactured by Entegris certificates of regulatory compliance have been acquired from our suppliers.
2. This statement of Regulatory Compliance applies to standard cataloged Aramus single-use bags and assemblies. Custom single-use bags and assemblies may not meet or may not have been tested to some or all of these regulatory requirements. Contact Entegris for details.