





Product & Material - Approval Definitions

Product Approval		Definition	Website
	ISO 594 This has now been revised by ISO 80369-7	Specification of the requirements for conical (Luer) fittings for use with hyperdemic syringes and needles and with certain other apparatus for medical use such as transfusion and infusion sets. It covers fittings made of rigid and semi-rigid materials and includes test methods for gauging and performance. It excludes provision for more flexible or elastomeric materials. The annex on liquid leakage is given as an example	https://www.iso.org/standard/4693.html
	ISO 594-1 This has now been revised by ISO 80369-7	Specification of the requirements for conical (Luer) fittings for use with hyperdemic syringes and needles and with certain other apparatus for medical use such as transfusion and infusion sets. It covers fittings made of rigid and semi-rigid materials and includes test methods for gauging and performance. It excludes provision for more flexible or elastomeric materials. The annex on liquid leakage is given as an example	https://www.iso.org/standard/4693.html
	ISO 594-2 This has now been revised by ISO 80369-7	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings	https://www.iso.org/standard/29540.html
	ISO 10993 Compliant	Biological evaluation of medical devices	https://www.iso.org/standard/68936.html
	Class VI	Class VI testing is aimed to certify that there are no harmful reactions or long-term bodily effects caused by chemicals that leach out of plastic materials	
Material Approval		Definition	Website
 U.S. FOOD & DRUG ADMINISTRATION	21 CFR 177.1500 FDA Approved Nylon Resins	Food Equipment Materials sets minimum public health and sanitation guidelines for materials used in the construction of commercial food equipment. It is applicable to the materials and finishes used for broilers, beverage dispensers, cutting boards, stock pots, etc. It is also applicable to components like tubing, sealants, gaskets, valves, and other items intended for an assortment of food equipment applications	https://www.govinfo.gov/app/details/CFR-2002-title21-vol3/CFR-2002-title21-vol3-sec177-1500
	21 CFR 177.1520 FDA Approved Olefin polymers		https://www.govinfo.gov/app/details/CFR-2011-title21-vol3/CFR-2011-title21-vol3-sec177-1520
	21 CFR 177.1580 FDA regulation Polycarbonate resins		https://www.govinfo.gov/app/details/CFR-2011-title21-vol3/CFR-2011-title21-vol3-sec177-1580
	21 CFR 177.2500 FDA Approved Polyphenylene sulfone resins		https://www.govinfo.gov/app/details/CFR-2018-title21-vol3/CFR-2018-title21-vol3-sec177-2500
	21 CFR 177.1590 FDA Approved Polyester elastomers		https://www.govinfo.gov/app/details/CFR-2018-title21-vol3/CFR-2018-title21-vol3-sec177-1590

Material Approval		Definition	Website
	USP 87	USP 87 is designed to determine the biological reactivity of mammalian cell cultures following contact with elastomeric plastics and other polymeric materials with direct or indirect patient contact or of specific extracts prepared from the materials under test	http://www.usp.org/
	USP 88	USP 88 was developed as a series of tests packaged together in various iterations to become what is known as a Class Test. These classifications range from Class I through Class VI and as the classification increases, so does the number of extraction vehicles and number of tests required	
	USP 661	USP 661 is to provide standards for plastic materials and components used to package medical articles, such as pharmaceuticals, biologics, dietary supplements, and devices. Plastics are composed of a mixture of homologous polymers, having a range of molecular weights	
	NSF/ANSI 3	NSF/ANSI 3 establishes minimum public health and sanitation requirements for the materials, design, construction and performance of commercial dishwashing, glasswashing, and pot, pan, and utensil washing machines (such as stationary racks and conveyor machines) and their related components	http://www.nsf.org/services/by-type/standards-publications/food-equipment-standards
	NSF/ANSI 51	NSF/ANSI 51 establishes minimum public health and sanitation requirements for materials and finishes used in the manufacture of commercial foodservice equipment (such as broilers, beverage dispensers, cutting boards and stock pots) and its components (such as tubing, sealants, gaskets and valves)	http://www.nsf.org/services/by-type/standards-publications/food-equipment-standards
	NSF/ANSI 52	NSF/ANSI 52 establishes minimum public health and sanitation requirements for supplemental flooring for use in food preparation, dry storage and warewashing areas. This includes requirements for cleanability, durability, and resistance to the use environment, microbiological growth and vermin	http://www.nsf.org/services/by-type/standards-publications/food-equipment-standards
	NSF/ANSI 62	Distillation systems heat water to the boiling point, and then collect the water vapor as it condenses, leaving behind contaminants such as heavy metals. Some contaminants that convert readily into gases, such as volatile organic chemicals, can carry over with the water vapor	http://www.nsf.org/consumer-resources/water-quality/water-filters-testing-treatment/standards-water-treatment-systems

* Please note, standards change all the time, this does not mean that the product will also be up to the latest standard/approval - please contact us for further information