

Pharma-Clear® R Series

Braided Reinforced Silicone Tubing

SaniSure Pharma Clear R is a polyester yarn reinforced inner braid tubing and developed for high pressure tubing applications. The platinum silicone that encapsulates the polyester yarn is our Pharma-Clear 65 series and is tested to the same stringent biological and chemistry standards in order to meet or exceed all EU and USFDA regulations for pharmaceutical use.

- ISO Class 7 cleanroom manufacturing
- Standard and custom sizes available
- Manufactured for pharmaceutical and biopharmaceutical

Key Features

- Platinum cured Silicone with polyester inner reinforcement
- Hardness: durometer 61 Shore A
- Excellent Clarity polyester Reinforced for high pressure applications
- Tasteless, odorless
- Contains no phthalate plasticizers or peroxides that can leach out into process fluid
- Low-binding surface minimizes absorption of proteins and food products
- Sterilization Methods: autoclave, gamma irradiation, and chemical sterilants
- Packaging: Double bagged
- Working Low Temperature Range: -100°F (-73.3°C)
- Working High Temperature Range: 400°F (204.4°C)

Compliance

- Inner tube has passed:
- U.S. Pharmacopeia 43, National Formulary 38 (USP), General Chapter <88> Class VI, Biological Reactivity Tests, In Vivo (2020)
- U.S. Pharmacopeia 43, National Formulary 38 (USP), General Chapter <87> Class VI, Biological Reactivity Tests, In Vitro (2020)
- ISO 10993 (various parts)
- Request our comprehensive extractables and biocompatibility study for this product: sanisure.com/resources

Applications

- High Pressure transfer line
- Steam in Place (SIP)
- Load Cells Hoses
- Process Hoses

Pharma-Clear® R Series
Braided Reinforced Silicone Tubing

Regulatory Testing

Biocompatibility USP <87> and USP <88>[2]	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP <87> • USP <88>
Biocompatibility Cont. (ISO 10993 and USP Class VI)[1]	A Representative sample of the compound used to manufacture this product has been tested according to ISO 10993 and USP Class VI testing requirements. The sample met the requirements of the following tests: • Systemic Injection Test (USP Class VI and ISO 10993) • Intracutaneous Toxicity Test (USP Class VI and ISO 10993) • Intramuscular Implantation Test (USP Class VI and ISO 10993) • Agar Diffusion (ISO 10993-5) • L929 MEM Elution (ISO 10993-5) • Implant Effects (ISO 10993-6) • Sensitization (Kligman Maximization) (ISO 10993-10) • Systemic Toxicity (ISO 10993-11)
Extractables - USP[2]	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP <665> • USP <661.2>
Extractables - FDA Food Contact[1]	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • FDA 21 CFR 177.2600
Endotoxin Testing[2]	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP< 85>
Particulate Testing[2]	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP <788>

[1]The biocompatibility information listed in this section is based on information provided by our compound source. Testing is based on single lots, although lot-to-lot variance would not be expected to show different results.

[2]The assessment is available upon request at: https://sanisure.com/resources/
Validation Package With Extractable Report (BPOG) available up request.

Regulatory Compliances

Based on the information made available to us by our raw material supplier, the above material is compliant to the below list of regulatory requirements.

- RoHS Compliant
- REACH Compliant
- Conflict Minerals
- California Propositon 65
- ICH Q3D Guideline for elemental impurities
- EU Persistent Organic Pollutants (POPs)

Presence of Substance

Based on the information made available to SaniSure by its material supplier, none of the following compounds are intentionally added in as a 'raw material' or as a 'process aid' to the above product:

- Bisphenol A (BPA)
- Melamine
- Latex
- N-Nitrosamines
- Phthalates
- Slip Agents
- Polyvinyl chloride (PVC)

Pharma-Clear® R Series
Braided Reinforced Silicone Tubing

Animal Derivatives, Plant Derivatives, BSE/TSE Statement*

This product line is formulated from entirely synthetic ingredients; therefore, these polymers contain no animal by products, no substances of animal or plant origin, nor are the polymers derived from specified risk materials for BSE/TSE.

*Please note that the information provided is based on best available knowledge; we do not test for the presence of trace amounts of substances that may be introduced our products as contaminants. We do not routinely analyze our products for the presence of the above reportable substances; however, based on information provided by our supplier and to the best of our knowledge, the above material is free from animal derivatives.

Genetically Modified Organisms (GMO)
This product is not manufactured with any genetically modified organisms (GMO's).

Allergens

Based on the information provided to SaniSure by its supplier and our documentation reviews, we have found that the product listed above does not intentionally contain any of the below allergens

- Gluten
- Lactose
- Nuts
- Egg/Protein
- Soy
- Nickel
- Zinc
- Fish/Shellfish

Manufacturing Standard

The above material is manufactured in an ISO 9001:2015 accredited facility. Furthermore, this product is manufactured in an ISO 14644-1 Class 7 cleanroom.

Dimensional Tolerance

Inside and outside diameter tolerances are maintained to RMA E1 tolerances.

Sterilization

Gamma Irradiation:
The recommended maximum dosage for gamma irradiation of the above product is 50 kGy. When required of SaniSure, the standard range for gamma irradiation of products is between 27.5 and 40 kGy.

Autoclave:
The above product is generally compatible with autoclave sterilization. Please note that users must validate their sterilization conditions and procedure to ensure this product is suitable for a particular application. Below are some examples of common autoclave conditions:

- 30 minutes at 121°C (250°F)
- 10 minutes at 132°C (270°F)

Shelf Life and Storage Conditions

If stored according to the following recommendations, SaniSure recommends that customers dispose of this product after five (5) years from the date of manufacturing. Store this product in an ambient temperature and humidity environment. The product should be free from exposure to direct outside weather influences and stored in a dark space out of direct contact with light. The area should be free from volatile solvents, corrosive gases, or other potentially harmful vapors. Stack the product flat in an opaque container during storage. The container should be kept off the floor (e.g., on shelving or skids) and remain closed and sealed while in storage. The product should be free of kinking and not be subjected to crushing forces from the weight of the product above it.

SaniSure makes no representations or warranties as to the accuracy of the information contained or referenced herein. Most results mentioned above are based on single lots of material. Although a lot-to-lot variance would not be expected to show different results, this data should not be construed as a warranty of fitness for use. Prior to use for any application, the user has the sole responsibility for determining the suitability of these products in any application.

Sparta SaniSure®, Inc.

18 White Lake Road
Sparta, NJ 0787
New York, USA
+1 973 383 2834
SalesSupport-US@sanisure.com

Stapleford SaniSure®, Ltd.

49 Pasture Road
Stapleford, Nottingham
UK NG9 8HR, United Kingdom
+352 2633731
SalesSupport-US@sanisure.com

sanisure.com

SANISURE®
Solution Based Innovation

Specifications subject to change without notice. Copyright SaniSure GmbH. DE, Version 01



Pharma-Clear® R Series

Sizing Chart Standard Offerings

Part Number	ID		OD		Wall Thickness		Working Pressure (psi)	Burst Pressure (psi)	Vacuum Rating (hg)	Bend Radius(in)
	(inch)	(mm)	(inch)	(mm)	(inch)	(mm)				
PLTS-R-125-50-A	1/8"	3.2	.375"	9.6	.125"	3.2	175	525	29.5	0.5
PLTS-R-187-50-A	3/16"	4.8	.460"	11.7	.136"	3.45	170	510	29.5	0.75
PLTS-R-250-50-A	1/4"	6.4	.500"	12.7	.125"	3.2	140	420	29.5	1
PLTS-R-375-50-A	3/8"	9.5	.625"	15.9	.125"	3.2	140	420		
PLTS-R-500-50-A	1/2"	12.7	.875"	22.2	.188"	4.8	105	315	10	2.75
PLTS-R-625-50-A	5/8"	15.9	.990"	25.1	.183"	4.6	100	300	10	3.25
PLTS-R-750-50-A	3/4"	19.1	1.125"	28.6	.188"	4.8	90	270		
PLTS-R-1000-50-A	1"	25.4	1.405"	35.6	.202"	5.1	60	180		

NOTE: Product properties may be affected greatly by temperature, operating pressure, chemical concentration, the presence of other chemicals, and other factors. Ultimately, users should determine the compatibility of any product through thier own performance qualifications under their particular process conditions. Specifications on this page are subject to change without notice.

NOTE: Standard coil length is 50 feet. Other length and spools available, consult factory.

Custom sizes available

Vacuum Rating
NOTE: Testing conducted on tubing maintained in a straight configuration (no bends) at a standard laboratory temperature of 23°C ÷ 2°C, in accordance with ISO 7233 Method A

Working Pressure:
based on 70°F (21.1 °C)

Working Pressure:
based on a 3:1 burst factor

Tubing has printing
Can also have no print (NP) as an option

Please contact our quality department for the most up-to-date regulatory information. Specifications in this document are subject to change without notice.

heleon group

Van der Waalsweg 13, 3241ME
Middelharnis, The Netherlands

+31 187 890 900

Heleon-Group.com

SANISURE® Solution Based Innovation

Specifications subject to change without notice. Copyright SaniSure GmbH. DE, Version 01