MANUFACTURE

Country of Origin
PharMed® BPT is manufactured in the U.S.A, France, and in China.

Manufacturing Location
PharMed® BPT is manufactured in the U.S.A, France, and in China.

Saint-Gobain Performance Plastics
2664 Gilchrist Road
Akron, OH 44305
USA
Tel: +1 (330) 798-9240

Saint-Gobain Performance Plastics
34 rue du moulin des Aulnaies
Charny-Orée-De-Puisaye
France
Tel: (+33) 3 86 63 78 78

Saint-Gobain Performance Plastics
1476 Kunyang Road
Minhang District
Shanghai, China
Tel: (+86) 21-5472-1568

Materials of Construction
PharMed® BPT is a proprietary thermoplastic elastomeric (TPE) formulation.

Certification
Standard Certificate of Conformance.

Storage Conditions
No special storage conditions. Products awaiting shipment are stored in ambient lighting, temperature and humidity condition. Ambient storage conditions consist of a cool, dry environment away from direct sunlight and in the original unopened packaging.

Shelf Life
The shelf life of PharMed® BPT tubing is three (3) years from the date of manufacture, when stored in the original shipping container under conditions of 0°C (32°F) to 49°C (120°F) and less than 80% Relative Humidity.

STANDARDS TESTING

USP Class VI
PharMed® BPT meets the requirements of the USP, Biological Test for Plastics, Class VI.

ISO 10993
PharMed® BPT meets the requirements of ISO 10993-3, 10993-4, 10993-5, and 10993-11.

EP
PharMed® BPT meets European Pharmacopoeia 3.2.9.

PRODUCT STEWARDSHIP

BSE/TSE
PharMed® BPT is compliant with EMA/410/01 Rev. 3.
Bisphenol A (BPA)
Bisphenol A is not used in the formulation or manufacture of PharMed® BPT.

Latex
Latex is not used in the manufacture of PharMed® BPT. PharMed® BPT does not come in contact with latex materials during the manufacturing or packaging process.

Persistant Organic Pollutants
In accordance with the Stockholm Convention of 2009, EC850/2004, and EU 757/2010, Persistant Organic Pollutants (POP), are not used in the formulation or manufacture of PharMed® BPT. This includes, but is not limited to, Perfluorooctanoic acids (PFOA), Perfluoroctane sulfonates (PFOS), Polychlorinated biphenyls (PCB), Dioxins, Furans, and Polyaromatic hydrocarbons (PAH).

Restriction of Hazardous Substances (RoHS)
PharMed® BPT is in compliance with RoHS requirements per directives 2015/863/EU. None of the currently listed RoHS exemptions are used in the manufacture of this product.

REACH Registration, Evaluation, Authorization and Restriction of Chemicals (EC 1907/2006)
The European Union REACH regulation of December 18, 2006 requires companies which manufacture or import chemical substances into the European Union in quantities of one metric ton or more per year to register these substances with the European Chemicals Agency (ECHA). Saint-Gobain Performance Plastics complies with the provisions of REACH where applicable.

PharMed® BPT products do not contain materials described as Substances of Very High Concern (SVHC) as defined by the European Union/ECHA.

Conflict Minerals
There is no instance of Conflict Minerals, as defined by the Dodd-Frank Act, used in the manufacture of PharMed® BPT.

OPERATIONAL

Gamma Range
All components are compatible with gamma irradiation up to 50 kGy.

RESPONSIBILITY

This Regulatory Information Overview document is intended to provide users of Saint-Gobain PharMed® BPT with the information necessary to assess the suitability of these products for use in their intended application.

Saint-Gobain has not run an analysis for concentration levels for the materials listed in the above regulatory compliance statements but relies on raw material suppliers and Saint-Gobain manufacturing controls for this information. It is the responsibility of the customer to determine whether their use of Saint-Gobain products is safe, lawful (except as provided in the above certifications) and technically suitable for their intended purpose.