

Material Code M0598

Revision 00

Type PP
 Brand name P5M6K-080
 Supplier FLINT HILLS

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	up to 6Mrads
Ethylene Oxide	YES	-
Autoclave	YES	This product is not recommended for autoclave sterilization in the presence of aqueous solutions.
E-Beam	YES	up to 50KGy

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	USP	met the requirements
Cytotoxicity	YES	ISO 10993-5	no cytotoxicity was noted

Main Regulatory Compliances:

	<u>Compliant</u>	<u>Comments</u>
BPA	YES	Not used in the manufacturing process
CONEG (Cadmium, chromium, lead and mercury)	YES	Not used in the manufacturing process
Conflict Minerals	YES	Not used in the manufacturing process
Drug Master File	YES	-
Food Contact	NO	This material does not meet the requirements of Regulation 10/2011 for food contact as it contains an additive not present
European Directive (2004/12/EC) Packaging and Packaging Waste	YES	-
European Directive 2002/16/EC - Epoxy Derivatives	YES	Not used in the manufacturing process
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
European Directive 2003/11/EC	YES	Not used in the manufacturing process
European Pharmacopoeia	NO	This product has not been tested to the EP 3.1.3 or 3.1.6 monographs for Polyolefines or Polypropylene for Containers for
Latex or Natural Rubber	YES	Not used in the manufacturing process
Phthalates	YES	Not used in the manufacturing process
Polyvinyl Chloride (PVC)	YES	Not used in the manufacturing process
TSE / BSE	YES	Not used in the manufacturing process
European Directive (EC 1907/2006) REACH	YES	-
SVHC List	YES	Not used in the manufacturing process
MSDS	YES	-

Technical Characteristics:

	<u>Value</u>	<u>Measuring Method</u>	<u>Comments</u>
Injection	YES	-	-
Density	0.90 g/cm3	ASTM D1505	-
Color	colorless	-	-
Melt Flow Rate	27.0 g/10 min	ASTM D1238	-
Tensile Strength at Break			-
Tensile Elongation at Break	14 % yield	ASTM D638	-
Tensile Strength at Yield	31 MPa	ASTM D638	-
Hardness	85 R	ASTM D785	Rockwell Hardness

R&D Validation	FRA	QA/RA Validation	CGI
Date	25-08-2017	Date	23-11-2017

Please be aware regarding Medical Applications, Technical Characteristics and Regulatory requirements:

Promeppla Group does not test or analyze this material for any specified regulatory requirements nor for the any technical data. The information provided by the raw material manufacturers has been compiled by Promeppla Group, in a readily retrievable format, as part of our service to you, our customer. Customers and End-Users must themselves determine suitability of use and conduct The Sterilisation Data presented herein, is provided solely for informative purposes only. The Sterilisation stability must be validated by the Customer and/or the End-User. We remain at your disposal should you need any additional information.