PROMEPLA

Material Certificate

Material Code M0053 **Revision** 00

Type PA
Brand name Zytel 101F Nylon Resin
Supplier DuPont

Sterilization Stablity:

	Compliant	Comments
Gamma Sterilization	YES	-
Ethylene Oxyde	YES	-
Autoclave	YES	-

Biocompatibility Data:

	Compliant	Standard	Comments

Main Regulatory Compliances:

	Compliant	Comments
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
Food Contact	YES	FDA 21CFR 177.1500
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
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	Contains minor quantity of a component derived from bovine tallow sources. Subjected to rigorous processes of hydrolysis
European Directive (EC 1907/2006) REACH	YES	-
SVHC List	YES	Not used in the manufacturing process
MSDS	YES	-

Technical Characteristics:

	Value	Measuring Method	Comments
Injection	YES	-	-
Density	1140/- kg/m^3	ISO 1183	-
Viscosity	140/* cm^3/g	ISO 307, 1157, 1628	-
Modulus of Elasticity / Young modulus	1400 MPa	ISO 527-1/ -2	-
Tensile Elongation at Break	> 50%	ISO 527-1/ -2	-
Tensile Strength at Yield	55 MPa	ISO 527-1/ -2	-

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