PROMEPLA

Material Certificate

Material Code M0933 **Revision** 00

Type	PC
Brand name	Lexan HP2REU
Supplier	SABIC

Sterilization Stablity:

	Compliant	Comments
Gamma Sterilization	YES	up to 25kGy
Ethylene Oxyde	YES	-
Autoclave	YES	-

Biocompatibility Data:

	Compliant	Standard	Comments
USP Class VI	YES	USP	-
Cytotoxicity	YES	ISO 10993-5	-
Sensitization	YES	ISO 10993-10	-
Irritation or intracutaneous reactivity	YES	ISO 10993-10	-
Systemic toxicity (acute)	YES	ISO 10993-11	-
Implantation	YES	ISO 10993-6	-
Hæmocompatibility	YES	ISO 10993-4	-

Main Regulatory Compliances:

	Compliant	Comments
BPA	NO	< 100ppm
Food Contact	YES	-
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
TSE / BSE	YES	No BSE risk
US Pharmacopoeia	YES	Class VI
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	1.2 g/cm3	ISO 1183	-
Color	Various - Natural	-	-
Melt Flow Rate	22 g/10 min	ASTM D 1238	300°C/1.2 kgf
Modulus of Elasticity / Young modulus	2350 MPa	ISO 527	1 mm/min
Tensile Strength at Break	65 MPa	ISO 527	50 mm/min
Tensile Strength at Yield	63 MPa	ISO 527	50 mm/min
Other mechanical property 1	6%	ISO 527	tensile strain, yield 50 mm/min
Other mechanical property 2	90 MPa	ISO 527	fluxural stress, yield 2mm/min

R&D Validation	FRA	**QA/RA Validation**	CGI
Date	25-08-2017	**Date**	13-09-2017