

Material Code M0071

Revision 01

Type ABS
Brand name TERLUX 2802 TR
Supplier STYROLUTION/ BASF

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	-
Ethylene Oxyde	YES	-

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	-	-

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
Food Contact	YES	21 CFR 177.1030
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
European Directive 2012/19/UE - WEEE	YES	No deliberately added brominated flame retardants
European Pharmacopoeia	YES	-
Latex or Natural Rubber	YES	Not used in the manufacturing process
Phthalates	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	this product does not contain any of the substances of very high concern above a limit of 0.1%

Technical Characteristics:

	<u>Value</u>	<u>Measuring Method</u>	<u>Comments</u>
Injection	YES	-	-
Density	1,08 g/cm3	ISO 1183	-
Color	Naturel, Red, Blue	-	-
Melt Flow Rate	2 cm3/10min	ISO1133	MVR 220°C/10kg
Modulus of Elasticity / Young modulus	2000 MPa	ISO 527	-
Tensile Strength at Yield	48 MPa	ISO 527	-
Hardness	70 MPa	ISO 2039-1	Ball indentation hardness

R&D Validation	FRA	QA/RA Validation	CGI
Date	25-08-2017	Date	12/09/17

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.