

Material Code M0642

Revision 00

Type PVC
Brand name 8577G-015 ou ATB 8540B
Supplier COLORITE EUROPE ou TeknipleX

Sterilization Stability:

	Compliant	Comments
Gamma Sterilization	YES	-
Ethylene Oxyde	YES	-

Biocompatibility Data:

	Compliant	Standard	Comments
USP Class VI	YES	USP	-
Cytotoxicity	YES	ISO 10993-5	-
Hæmocompatibility	YES	ISO 10993-4	-

Main Regulatory Compliances:

	Compliant	Comments
BPA	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	Not used in the manufacturing process
European Directive (EC 1907/2006) REACH	YES	-
MSDS	YES	-

Technical Characteristics:

	Value	Measuring Method	Comments
Extrusion	YES	-	-
Color	blue	-	-
Modulus of Elasticity / Young modulus	1600 psi	ASTM D-638	-
Tensile Strength at Break	2695 psi	ASTM D-638	-
Tensile Elongation at Break	355 %	ASTM-638	-
Hardness	85 shore A	ASTM D-2240	-

R&D Validation	FRA	QA/RA Validation	CGI
Date	25-08-2017	Date	09/06/2017

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.