

Material Code **M0358**

Revision **00**

Type PVC
Brand name Nakan-FTA 805R T100
Supplier RESINOPLAST/Arkema

Sterilization Stability:

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

Biocompatibility Data:

Compliant	Standard	Comments
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Main Regulatory Compliances:

	Compliant	Comments
BPA	YES	Not used in the manufacturing process
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	NO	32%
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	-	-
Density	1.22 N/A	ISO 1183	-
Color	Transparent	-	-
Tensile Strength at Break	>19 MPa	ISO 527	-
Tensile Elongation at Break	>410 %	ISO 527	-
Hardness	75 ShA	ISO 868	-

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:

Promepla 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 Promepla 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.