

Material Code M0021

Revision 00

Type PVC
Brand name NAKAN RMA 705NT01
Supplier ARKEMA/ RESILIA

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Ethylene Oxide	YES	-

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	-	-
Cytotoxicity	YES	EN/ ISO10993-5	-
Sensitization	YES	EN/ ISO10993-10	-
Hæmocompatibility	YES	EN/ ISO10993-4	-

Main Regulatory Compliances:

	<u>Compliant</u>	<u>Comments</u>
BPA	YES	Not used in the manufacturing process
Conflict Minerals	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	-
SVHC List	YES	Not used in the manufacturing process
MSDS	YES	-

Technical Characteristics:

	<u>Value</u>	<u>Measuring Method</u>	<u>Comments</u>
Injection	YES	-	-
Density	1.35 kg/dm3	ISO 1183	-
Other Property 1	70°C ±2	ISO 306/B	Vicat point (5kg)
Tensile Strength at Break	35-40 MPa	ISO 527	-
Tensile Elongation at Break	110-160 %	ISO 527	-
Hardness	82±2 ShD	ISO 868	-

R&D Validation	GVA	QA/RA Validation	ABA
Date	10/05/17	Date	10/05/17

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.