

**Material Code M0170**

**Revision 00**

**Type** PVC  
**Brand name** NAKAN FMM 871N T01  
**Supplier** RESILIA

**Sterilization Stability:**

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	and Beta Up to 25kGy
Ethylene Oxyde	YES	-

**Biocompatibility Data:**

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	-	-
Cytotoxicity	YES	ISO 10993-5	-
Sensitization	YES	ISO 10993-10	-
Irritation or intracutaneous reactivity	YES	ISO 10993-10	-
Systemic toxicity (acute)	YES	ASTM F 750-82	USP XXVIII Ed. 2005
Implantation	YES	USP XXVIII Ed. 2005	-
Hæmocompatibility	YES	ISO 10993-4	-

**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
European Pharmacopoeia	YES	ECC Pharmacopoeia 3.1.1.2 ed 5.02
Latex or Natural Rubber	YES	Not used in the manufacturing process
Phthalates	NO	quantity 26%
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>
Extrusion	YES	-	-
Injection	YES	-	-
Density	1.25 kg/dm <sup>3</sup> ±0.02	ISO 1183	-
Tensile Strength at Break	17 - 21 MPa	ISO 527	-
Hardness	87 ShA ±2	ISO 868	At 23°C

<b>R&amp;D Validation</b>	GVA	<b>QA/RA Validation</b>	CGI
<b>Date</b>	12/05/17	<b>Date</b>	12/05/17

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.