

Material Code M0774

Revision 00

Type PTFE
Brand name MMT323
Supplier W.L. GORE

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	up 25KGy
Ethylene Oxyde	YES	-
E-Beam	YES	up 25KGy

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	USP	-
Cytotoxicity	YES	ISO 10993-5	-
Sensitization	YES	ISO 10993-10	-
Systemic toxicity (acute)	YES	ISO 10993-11	-
Hæmocompatibility	YES	ISO 10993-4	-
Carcinogenicity	YES	ISO 10993-3	-

Main Regulatory Compliances:

	<u>Compliant</u>	<u>Comments</u>
BPA	YES	Not used in the manufacturing process
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
European Directive 2003/11/EC	YES	Not used in the manufacturing process
Latex or Natural Rubber	YES	Not used in the manufacturing process
TSE / BSE	YES	Not used in the manufacturing process
European Directive (EC 1907/2006) REACH	YES	-

Technical Characteristics:

	<u>Value</u>	<u>Measuring Method</u>	<u>Comments</u>
Other Property 1	0.2 µm	-	Pore size
Other Property 2	0.36 mm	-	Thichness
Other Property 3	3.2 bar (46 psi)	-	Water entry pressure
Other Property 4	3.3 at 10.3 LPM/ cm ²	-	Airflow (1bar (15 psi))

Document status : VALID

R&D Validation	GVA	QA/RA Validation	CGI
Date	25-01-2018	Date	25-01-2018

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.