

Material Code M0041

Revision 00

Type MATERIAL
Brand name VERSAPOR V3000R
Supplier GELMAN/ PALL

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	-
Ethylene Oxyde	YES	-

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	-	-
Cytotoxicity	YES	-	-
Hæmocompatibility	YES	-	-

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	-
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 mechanical property 1	3 µm	-	Pore Size
Other mechanical property 2	152 - 305 µm	-	Thickness
Other mechanical property 3	> 154 mm Hg	-	WBT
Other mechanical property 4	> 54.8 l/m	-	Air Flow at 260 mmHg surface 3.7 cm ²

R&D Validation	GVA	QA/RA Validation	CGI
Date	12/05/17	Date	12/05/17

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.