

Virgin PTFE – FE1000 TPS

Date	Revision	Details of changes
June 2024	11	Format update

Caratteristiche Fisiche e Meccaniche Physical and mechanical Properties

Caratteristica Property	Metodo di prova Test method	U.M. Unit	Valore misurato Measured value
Densità Density	ASTM D 792	g/cm ³	2.18
Carico di rottura Tensile strength	ASTM D 4894	MPa	25
Allungamento a rottura Elongation at break	ASTM D 4894	%	300
Temperatura di utilizzo Range Temperature	-	°C	-200/+200

Caratteristiche Elettriche (tipiche da letteratura) Electrical Properties (typical from literature)

Caratteristica Property	Metodo di prova Test method	U.M. Unit	Valore misurato Measured value
Costante dielettrica Dielectric constant (50.10 ⁹ Hz)	ASTM D 150	-	2.10
Fattore di dissipazione Dissipation factor	ASTM D 150	-	< 0,0002
Resistività di volume Volume resistivity	ASTM D 257	Ω/cm	10 ¹⁷
Resistività di superficie Surface resistivity (2)	ASTM D 257	Ω	10 ¹⁵

I dati riportati sono suscettibili di variazioni che GAPI riterrà di apportare per migliorare le caratteristiche del prodotto. Le informazioni fornite sono indicative.
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Pressione di scoppio e raggio di curvatura min a temperatura ambiente Burst pressure and min bending radius at room temperature

Misure metriche - metric measure

\varnothing interno \varnothing inside	Spessore parete Wall thickness	Pressione di scoppio Burst pressure	Raggio curvatura min. Min.bending radius	\varnothing interno \varnothing inside	Spessore parete Wall thickness	Pressione di scoppio Burst pressure	Raggio curvatura min. Min.bending radius
mm	mm	bar	mm	mm	mm	bar	mm
1.00	0.50	120	10				
1.00	1.00	240	10				
1.50	0.50	80	15	8.00	1.50	45	160
1.50	0.75	120	15	8.00	2.00	60	75
2.00	0.50	60	20	9.00	0.50	13	200
2.00	1.00	120	20	9.00	1.00	27	125
2.00	1.50	180	20	9.00	1.50	40	100
2.50	0.50	48	25	9.00	2.00	53	80
2.50	0.75	72	25	10.00	0.50	12	245
2.50	1.00	96	20	10.00	1.00	24	145
3.00	0.50	40	35	10.00	1.50	36	115
3.00	1.00	80	25	10.00	2.00	48	100
3.00	1.50	120	25	11.00	0.50	15	195
4.00	0.50	30	50	11.00	1.00	22	180
4.00	1.00	60	40	11.00	1.50	33	170
4.00	1.50	90	35	12.00	0.50	10	220
4.00	2.00	120	30	12.00	1.00	20	200
5.00	0.50	24	75	12.00	1.50	30	150
5.00	1.00	48	50	13.00	0.50	9	250
5.00	1.50	72	45	13.00	1.00	18	225
5.00	2.00	96	40	13.00	1.50	28	170
6.00	0.50	20	100	14.00	0.50	9	300
6.00	1.00	40	65	14.00	1.00	17	260
6.00	1.50	60	55	14.00	1.50	26	230
6.00	2.00	80	50	16.00	1.00	15	325
7.00	0.50	17	130	16.00	1.50	23	240
7.00	1.00	34	85	17.00	1.00	14	300
7.00	1.50	51	70	17.00	1.50	21	270
7.00	2.00	69	65	18.00	1.00	13	300
8.00	0.50	15	165	18.00	1.50	20	260
8.00	1.00	30	100	19.00	1.00	13	445
				19.00	1.50	19	325

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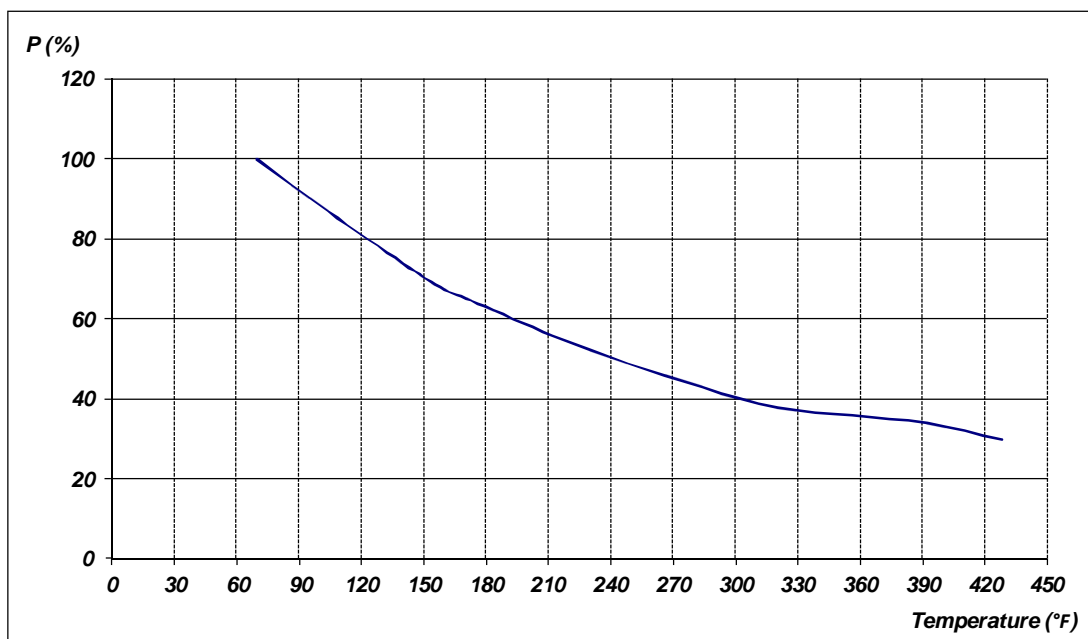
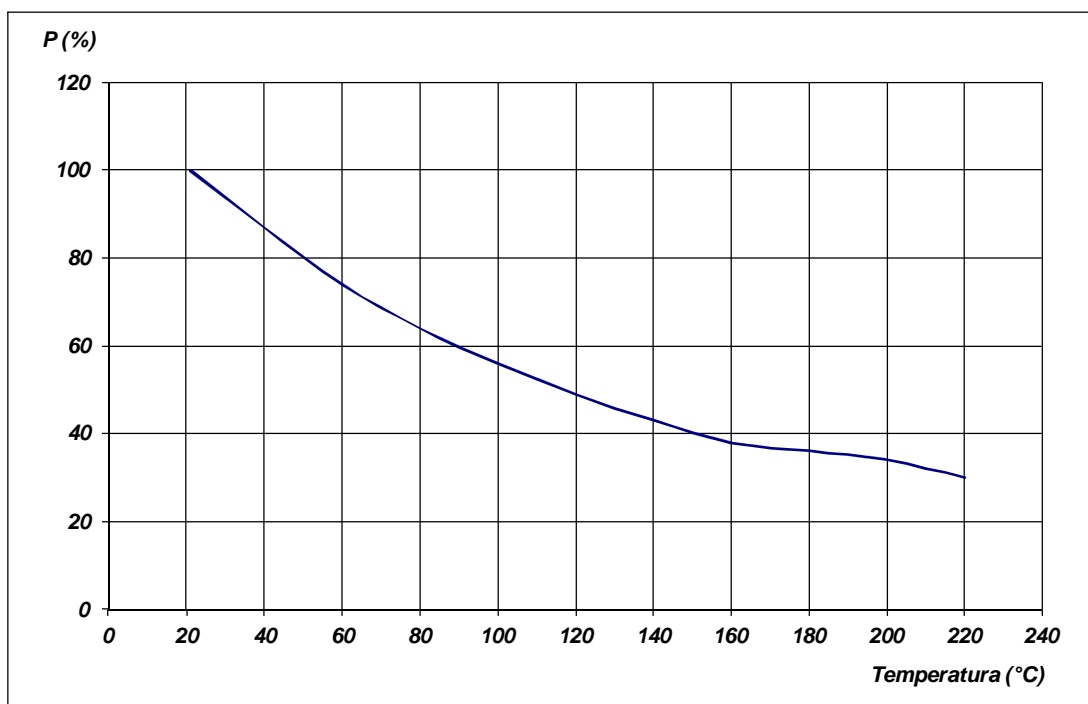
Dimensioni frazionarie - Fractional size

Ø interno	Ø esterno	Pressione di scoppio		Raggio di curvatura min.	
<i>Inside Ø</i>	<i>Outside Ø</i>	<i>Burst pressure</i>	<i>bar</i>	<i>PSI</i>	<i>Min. bending radius</i>
		<i>bar</i>	<i>PSI</i>	<i>mm</i>	<i>inch</i>
1/32	1/16	130	1885	10	0.394
1/32	3/32	250	3625	15	0.591
1/16	1/8	124	1798	15	0.591
1/16	3/16	249	3610	10	0.394
3/32	5/32	83	1203	20	0.787
1/8	3/16	62	899	30	1.181
1/8	1/4	123	1783	25	0.984
5/32	1/4	75	1087	35	1.378
3/16	1/4	41	594	50	1.969
3/16	5/16	83	1203	40	1.575
1/4	5/16	31	449	70	2.756
1/4	3/8	62	899	60	2.362
0.275	3/8	45	652	51	2.008
5/16	3/8	24	348	115	4.528
5/16	7/16	50	725	160	6.299
3/8	7/16	20	290	200	7.874
3/8	1/2	41	594	105	4.134
7/16	1/2	17	246	180	7.087
1/2	9/16	15	217	225	8.858
1/2	5/8	31	449	160	6.299
9/16	5/8	13	188	260	10.236
5/8	11/16	12	174	325	12.795
11/16	3/4	11	159	350	13.780
11/16	13/16	22	319	200	7.874

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Pressione di scoppio vs temperatura

Burst pressure reduction vs temperature



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Certificazioni/Certifications

Material conforms at food contact, in accordance with:

Italian regulations: DPR777, DL108, DM 34, DM174/04

EU regulations: 1935/2004/EC-10/2011/EU-2023/2006/EC

USA regulations: FDA 21 cfr § 177.1550

Material conforms at: *USP class VI*



UL - *UL 224 certified product*

Virgin PTFE – FE1000 TPS

  	
RAPPORTO DI PROVA / TEST REPORT	
NUMBER 1557\FPM\FDC\20	ISSUE DATE 27/10/2020
BUSINESS AREA BA Product Conformity Assessment	LABORATORY Food Contact
SPECIMEN DESCRIPTION PTFE FE1000 – TPS	
CUSTOMER GAPI SPA VIA MOLINARETTI, 2 24060 CASTELLI CALEPIO (BG)	
REFERENCE STANDARD D.P.R. 777 dated 23/08/1982, D.L. 108 dated 25/01/1992, D.M.34 dated 21/3/73 and subsequent updating. Regulation 1935/2004/EC GUCE L 338 dated 13/11/04 Regulation 10/2011/EU, GUUE L 12 dated 15/01/2011, and subsequent updating. UNI EN 1186 1+15:2003 (see the overall migration test description for the identification of the technical standard part)	
Pag. 1 di/of 12	
GQ001 REV.00 CSI S.p.A. A SOCIO UNICO SOCIETA' AD ATTIVITA' DI DIREZIONE E COORDINAMENTO DI IMQ GROUP S.p.A. REA MI 1466310 R.I./C.F./P.I. 11560160151 Cap. Soc. € 1.040.000 Sede legale Italia 20030 Senago (MI) Cascina Traversagna 21 direzione-cs@legaima.it info@csi-spa.com www.csi-spa.com	

Virgin PTFE – FE1000 TPS



RAPPORTO DI PROVA / TEST REPORT

NUMBER	ISSUE DATE
1708\FPM\FDC\20	11/11/2020

BUSINESS AREA	LABORATORY
BA Product Conformity Assessment	Food Contact

SPECIMEN DESCRIPTION

PTFE FE1000 - TPS

CUSTOMER

GAPI SPA
VIA MOLINARETTI, 2
24060 CASTELLI CALEPIO (BG)

REFERENCE STANDARD

FDA 21 cfr. § 177.1550

G0001 REV.00

CSI S.p.A., A SOCIO UNICO
SUCCESSA ALL'ATTIVITÀ DI DIREZIONE E
COORDINAMENTO DI IMQ Group S.p.A.

REA MI 1466310
R.I./C.F./P.I. 11360160151
Cap. Soc. € 1.040.000

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Pag. 1 di/of 6

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Virgin PTFE – FE1000 TPS**CERTIFICATE OF COMPLIANCE**

Certificate Number 20150818-E475089
Report Reference E475089-20150818
Issue Date 2015-AUGUST-18

Issued to: GAPI SPA
Via Molinaretti 2
24060 Castelli Calepio Bg ITALY

This is to certify that representative samples of COMPONENT - TUBING, EXTRUDED INSULATING
Flexible Not Heat Shrinkable PTFE Tubing,
Thin Walled Tubing PTFE FE 1000 TPS

Have been investigated by UL in accordance with the Standard(s) indicated on this Certificate.

Standard(s) for Safety: UL 224 and CSA-C22.2 No. 198.1, Extruded Insulating Tubing

Additional Information: See the UL Online Certifications Directory at www.ul.com/database for additional information

Only those products bearing the UL Certification Mark should be considered as being covered by UL's Certification and Follow-Up Service.

Recognized components are incomplete in certain constructional features or restricted in performance capabilities and are intended for use as components of complete equipment submitted for investigation rather than for direct separate installation in the field. The final acceptance of the component is dependent upon its installation and use in complete equipment submitted to UL LLC.

Look for the UL Certification Mark on the product.


Bruce Mahemholz, Director North American Certification Program
UL LLC

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		FOR THE MEDICAL INDUSTRY WORLDWIDE
		P.O. Box 140 • 1001 Proctor Drive • Elkhorn, WI 53121-0140
		Phone: (262) 723-5669 • Fax: (262) 723-4015
		www.genevalabs.com
REPORT TO:	Mr. Michael Rinaldi Gapi spa via Molinaretti 2 Castelli Calepio (BG), 24060 Italy	
TEST ARTICLE:	Virgin PTFE FE1000	
LOT NO:	Virgin PTFE FE1000	
P.O. NO.:	2	
DATE RECEIVED:	05-06-2021	
TEST INITIATION DATE:	05-26-2021	TEST COMPLETION DATE: 06-11-2021
TEST PROCEDURE:	Biological Reactivity Tests, In Vivo USP <88> Class Designation: VI	
Extraction Temperature:	50°C	Time: 72 Hours
According to the criteria outlined in the current USP <88>, the results of these studies indicates that the material <u>meets</u> the requirements for a USP Class <u>VI</u> .		
REFER TO REPORT NUMBERS:	Intracutaneous Injection: <u>TP17545</u> Systemic Injection: <u>TP17546</u> Implant: (7 Day Needle) <u>TP17547</u>	
ANALYST:	<u>Scott M. Robed</u>	DATE: <u>06-14-2021</u>
ACCEPTED BY:	<u>Jenny Tomomitsu</u> Technical Reviewer	DATE: <u>06-14-2021</u>
Q.A. SIGNATURE:	<u>E. Jane Muloney</u>	DATE: <u>06-14-2021</u>
Total Number of Pages:	22	