# *Virgin PTFE – FE1000 TPS*

Caratteristiche Fisiche e Meccaniche
***Physical and mechanical Properties***

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

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

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

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

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### *Dimensioni frazionarie - Fractional size*

| Ø interno *Inside Ø* | Ø esterno *Outside Ø* | Pressione di scoppio *Burst pressure* bar | PSI | Raggio di curvatura min. *Min. bending radius* mm | inch |
|---|---|---|---|---|---|
| 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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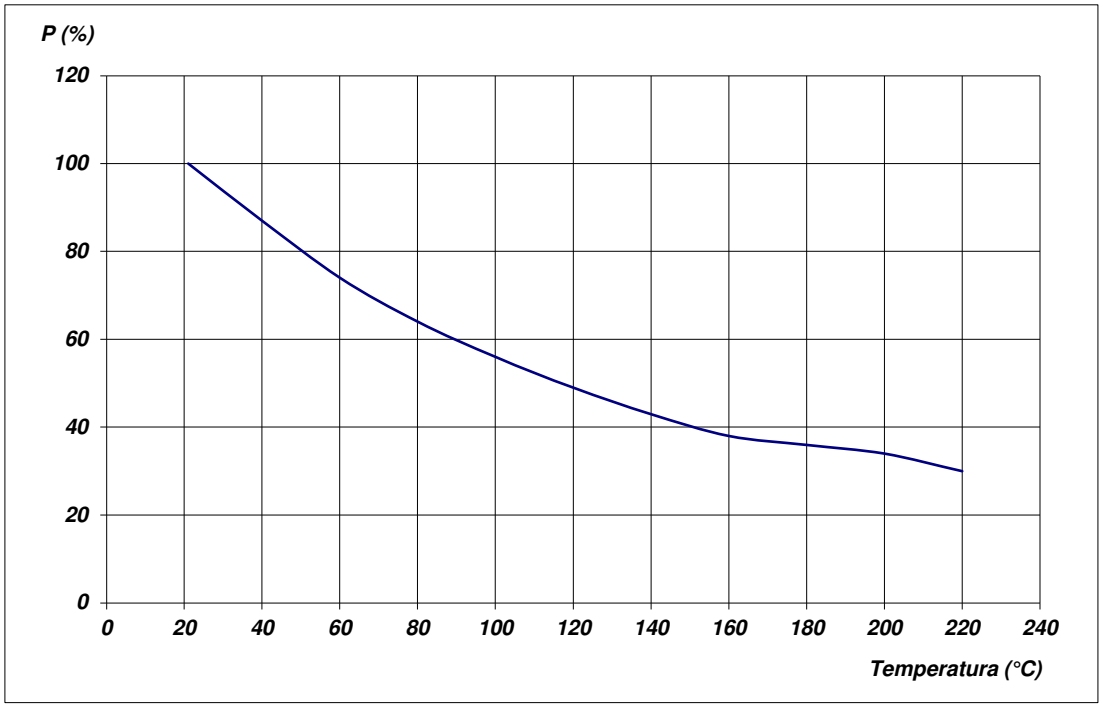
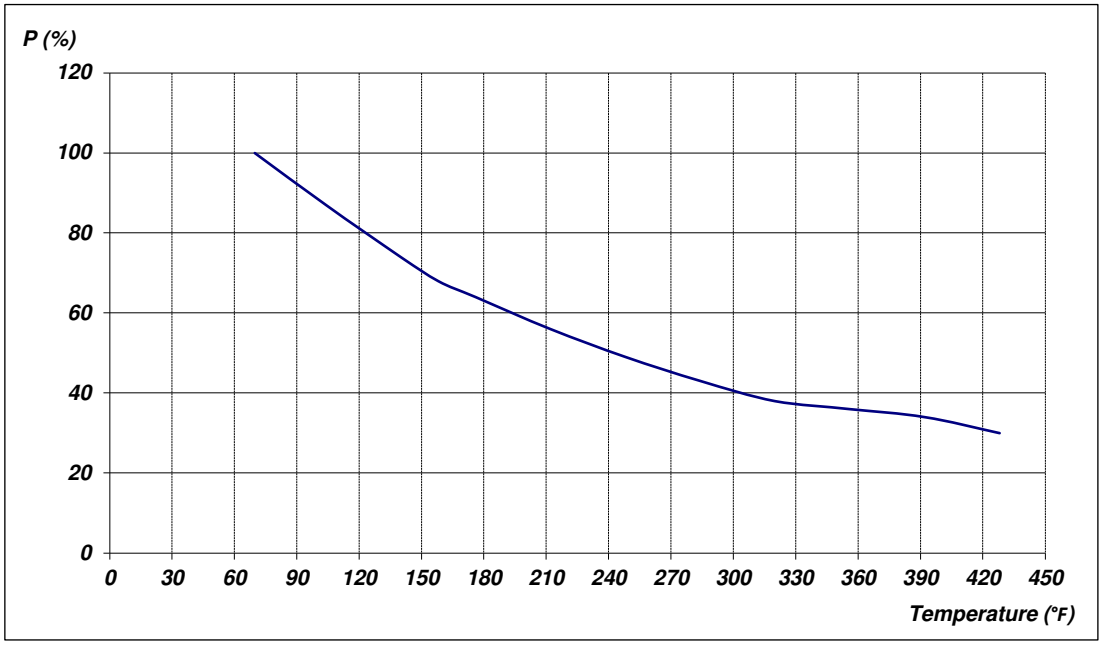
# *Virgin PTFE – FE1000 TPS*

## Pressione di scoppio vs temperatura
***Burst pressure reduction vs temperature***

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# *Virgin PTFE – FE1000 TPS*

## *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*

c UL us - *UL 224 certified product*

| *Date* | *Revision* | *Details of changes* |
|---|---|---|
| *27/04/2023* | *10* | *Revision certifications* |
| *17/01/2022* | *09* | *Update fractional size* |

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# *Virgin PTFE – FE1000 TPS*

CSI

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
LAB N°0004 L

## RAPPORTO DI PROVA / *TEST REPORT*

| NUMBER | ISSUE DATE |
|---|---|
| 1557\FPM\FDC\20 | 27/10/2020 |

| 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**

D.P.R. 777 dated 23/08/1982, D.L. 108 dated 25/01/1992, D.M.34 dated 21/3/73 and subsequent updatings.
Regulation 1935/2004/EC GUCE L 338 dated 13/11/04
Regulation 10/2011/EU, GUUE L 12 dated 15/01/2011, and subsequent updatings.
UNI EN 1186 1÷15:2003 (see the overall migration test description for the identification of the technical standard part)

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GQ001 REV.00

CSI S.p.A. A SOCIO UNICO SOGGETTA AD ATTIVITÀ DI DIREZIONE E COORDINAMENTO DI IMQ GROUP S.R.L.
REA MI 1466310
R.I./C.F./P.I. 11360160151
Cap. Soc. € 1.040.000
**Sede legale**
Italia | 20030 Senago (MI) | Cascina Traversagna 21
direzione-csi@legalmail.it | info@csi-spa.com | www.csi-spa.com

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# *Virgin PTFE – FE1000 TPS*

CSI

## 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**

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**REFERENCE STANDARD**

FDA 21 cfr. § 177.1550

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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<br>Via Molinaretti 2<br>24060 Castelli Calepio Bg ITALY |
| **This is to certify that representative samples of** | COMPONENT - TUBING, EXTRUDED INSULATING<br>Flexible Not Heat Shrinkable PTFE Tubing,<br>Thin Walled Tubing PTFE FE 1000 TPS<br><br>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 Mahrenholz, Director North American Certification Program
UL LLC

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JN21E0367
CLASS-A
TOK1010-4

GENEVA LABORATORIES
FOR THE MEDICAL INDUSTRY WORLDWIDE

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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 meets the requirements for a USP Class VI.

REFER TO REPORT NUMBERS:

Intracutaneous Injection: TP17545
Systemic Injection: TP17546
Implant: (7 Day Needle) TP17547

ANALYST: Scott M Robert DATE: 06-14-2021
ACCEPTED BY: Tammy Tomsmith DATE: 06.14.2021
Technical Reviewer
Q.A. SIGNATURE: Elaine Mulcahy DATE: 06-14-2021

Total Number of Pages: 22

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