



**S.I.F.R.A. EST S.P.A.**  
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 (Reg. Aut. F.V.G. decr. 150/art. 10/250)

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**TECHNICAL DATA SHEET**

**SIFLEX PACK®** Medical Grade PVC Bag  
 Product code: 0268 . . . . . (specific identification code)

Primary Component: Compound **SIFLEX®** SE0268EG Medical Grade PVC Granulate (used for lay-flat tube)

Secondary Component: Compound **SIFLEX®** SE0706EG Medical Grade PVC Granulate (used for tubing)

**NOTE:** Small color differences depend only on the color tone of the PVC resin.  
 This technical information consists of typical product data and should not be used as a specification.

**CHEMICAL SPECIFICATIONS**

Eur. Ph. Ed. in force

**TEST**

Alkalinity  
 Acidity  
 UV absorption  
 Reducing Substances  
 Appearance

**Limit Value**

0,8 HCl 0.01 M  
 0,4 NaOH 0.01 M  
 0,2 250/330nm  
 1,5 ml Na<sub>2</sub>S<sub>2</sub>O<sub>3</sub> 0.01 M  
 Clear, colourless

**GENERAL STATEMENT**

We hereby confirm that this product meets the requirements of the European Pharmacopoeia of not more than 40% of di(2-ethylhexyl)phthalate, less than 50 ppm for total incidental Heavy Metals and less than 1.0 ppm for Vinylchloride.

**BIOLOGICAL REACTIVITY**

USP XXIV

**TEST**

Test for Cytotoxicity  
 UNI EN ISO 10993-5  
 Acute Systemic injection test  
 in the Mouse  
 ASTM F 750-82  
 Intracutaneous Injection  
 in the Rabbit  
 UNI EN ISO 10993-10  
 Implantation Test in  
 the Rabbit  
 UNI EN ISO 10993-6  
 Hemolysis test  
 UNI EN ISO 10993-4  
 Bacterial Endotoxins Test  
 (LAL Test)  
 Physicochemical tests  
 - Plastics

**VALUE**

In Conformity  
 In Conformity  
 In Conformity  
 In Conformity  
 In Conformity  
 In Conformity  
 In Conformity  
 In Conformity

**PHYSICAL PROPERTIES**

The physical properties listed below are referring to the Primary Component .  
 Those of the Secondary Component instead, can be found in its specific technical data sheet.

**TEST**

Tensile strength at break  
 Elongation at break  
 Break at low temperature  
 Shore "A" durometer hardness  
 Density

**UNIT MEASURES**

MPa  
 %  
 °C  
 SH"A" (15"/23°C)  
 gr/cm<sup>3</sup>

**VALUE**

19  
 390  
 - 25° C  
 84 ± 2  
 1,23 ± 0.02

**PROCEDURE**

ISO 527  
 ISO 527  
 ISO 458  
 MAL 1-002  
 MAL 1-001

Date: 20/10/2009 – revision: 07  
 Date of issued: 20/10/09  
 Signature:

Date of verification: 20/10/09  
 Signature:

Date of approval: 20/10/09  
 Signature:

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