



**S.I.F.R.A. EST S.P.A.**  
 QUALITY CONTROL DEPARTMENT  
 APPROVED LABORATORY FOR APPLIED RESEARCH  
 (Reg. Aut. F.V.G. decr. 150/art. 10/250)

**S.I.F.R.A. EST S.P.A.**  
 tel.: +39 040 823602  
 Fax: +39 040 280605  
 e-mail: [info@sifraest.com](mailto:info@sifraest.com)  
<http://www.sifraest.com>

**TECHNICAL DATA SHEET**

**SIFLEX<sup>®</sup> Medical Grade PVC Granulate**  
 Product code: SE0002EG

**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

**FORMULATION**

- Not less than 55% of poly(vinyl chloride)
- Not more than 40% of di(2-ethylhexyl)phthalate
- Not more than 1% of zin octanoate (zinc 2-ethylhexanoate)
- Not more than 1% of calcium stearate or zinc stearate or 1% of a mixture of the two
- Not more than 1% of *N,N'* diacylethylenediamines (in this context acyl means in particular palmitoyl and stearoyl)
- Not more than 10% of one the following epoxidised oils or 10% or a mixture of the two
- Epoxidised soya oil of which the oxiran oxygen content is 6% to 8% and the iodine value is not greater than 6
- Epoxidised linseed oil of which the oxiran oxygen content is not greater than 10% and the iodine value is not greater than 7

**TEST**

- Alkalinity
- Acidity
- UV absorption
- Reducing Substances
- Residue on Evaporation
- Cadmiun
- Heavy Metals
- Appearance
- Tin
- Zinc
- Vinychloride
- Barium
- Calcium

**Limit Value**

- 1,0 ml HCl 0.01 M
- 1,5 ml NaOH 0.01 M
- 0,25 250/370nm
- 2,0 ml Na<sub>2</sub>S<sub>2</sub>O<sub>3</sub> 0.01 M
- 0,3 %
- 0,6 ppm
- 50,0 ppm
- Clear, colourless
- 20,0 ppm
- 0,2 %
- 1,0 ppm
- 5,0 ppm
- 0,0 %

**BIOLOGICAL REACTIVITY**

USP XXIV

**TEST**

- Test for Cytotoxicity
- Implantation Test in the Rabbit
- Hemolysis test
- Bacterial Endotoxins Test (LAL Test)

**VALUE**

- In Conformity
- In Conformity
- In Conformity
- In Conformity

**PHYSICAL PROPERTIES**

**TEST**

- Tensile strength at break
- Elongation at break
- Break at low temperature
- Shore "A" durometer hardness
- Density
- Water vapour trans. rate
- Oxygen permeability

**UNIT MEASURES**

- N/cm<sup>q</sup>
- %
- °C
- SH"A" (15"/48h)
- gr/cm<sup>3</sup>
- gr/(mq\*day\*bar)
- cm<sup>3</sup>/(mq\*day\*bar)

**VALUE**

- 1214
- 437
- 37° C
- 61 ± 2
- 1,178
- 4,9 to 23°C
- 440 to 23°C

**PROCEDURE**

- ASTM D-638
- ASTM D-638
- ASTM D-1043
- ISO 868
- ASTM D-792
- ASTM F-1249
- ASTM D-3985

Date: 20/10/2009 – revision: 11  
 Date of issued: 20/10/09  
 Signature:

Date of verification: 20/10/09  
 Signature:

Date of approval: 20/10/09  
 Signature:

The information contained herein is to our knowledge accurate and reliable as of the date of publication.  
 S.I.F.R.A. EST S.P.A makes no representations as to accuracy or completeness of the information contained herein and assumes no responsibility regarding the consequences of its use or for any printing errors. It is the customer's responsibility to inspect and test our products in order to satisfy himself as to the suitability of the product for the costumer's particular purpose. The customer is also responsible for the appropriate, safe and legal use, processing and handling of our products.