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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: 0068 (specific identification code)

Primary Component: Compound **SIFLEX[®]** SE0068EG Medical Grade PVC Granulate (used for lay-flat tube)

Secondary Component: Compound **SIFLEX[®]** SE0006EG 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 Na₂S₂O₃ 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/cm³

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: 09
 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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