

S.I.F.RA. EST S.P.A.

QUALITY CONTROL DEPARTMENT APPROVED LABORATORY FOR APPLIED RESEARCH (Reg. Aut. F.V.G. decr. 150/art. 10/250)

TECHNICAL DATA SHEET

Product code:

MAGIFLEX BAG

PVC-FREE bag

Magiflex BAG is a multilayers PVC-FREE Medical Bag: Magiflex tube and Magiflex film are based on a polyolefin copolimer.

Structure:

The films and the tube consist of three layers

Description: dimensions as specified by technical drawing

Storage and packaging: **MAGIFLEX BAG** must be stored at room temperature (not exceeding 40 °C) in closed and unbroken packaging, in order to avoid exposure to sunlight and water absorption. We suggest the use of product within 12 months after delivery.

referring to the Primary Component

TEST

Cytotoxicity test MEM elution Endotoxin test Metals and heavy metals

VALUE In Conformity In Conformity In Conformity

PROCEDURE

ISO 10993-5 Eur. Ph. 2.6.14 Eur. Ph. 3.1.3

FILM PROPERTIES			
TEST	UNIT MEASURES	VALUE	PROCEDURE
Tensile strength	МРа	22.9 ± 0.2	ISO 527
Elongation	%	580 ± 10	ISO 527
Modulus of Elasticity	Мра	142 ± 2	ISO 527
Water vepour transmission (25° C, 60% r.H)	gr/m²·d	< 0.70	DIN 53122
Oxygen transmission (23° C, 60% r.H)	ml/m² ·d·bar	< 0.70	DIN 53380
Residual ash	%	0.02	ISO 1887 /

Rev. 02 date 14/02/14

Issued by QA: Dott. Gobbo

Verified by RDQ: Dott. Maghetti

Approved by TD: Dott. Ravizza

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