



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)

TECHNICAL DATA SHEET

Product code:

MAGIFLEX

PVC-FREE Medical Films and Lay-flat

Magiflex is a multilayer PVC-FREE Medical Film, composed by polyolefin copolimer based, that is coextruded as tubular film and winded directly as lay-flat or cutting as a paired films.

Magiflex film is designed for the production of flexible containers and medical device addressed to the pharmaceutical industry

Structure: The films or the lay-flat consists of three layers
Description: thickness as specified by technical drawing (average of 10 measurements) width as specified by technical drawing
Storage: **MAGIFLEX** 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.
48h before use it should be stored within 18°C to 22°C
Recommended welding temperature approx. 140°C*
* this data is purely indicative as it depends on the machine used
Expyre date: Recommended use within 12 month after delivery

BIOLOGICAL REACTIVITY

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

Tensile strength
Elongation
Modulus of Elasticity
Water vepour transmission (25° C, 60% r.H)
Oxygen transmission (23° C, 60% r.H)
Residual ash

UNIT MEASURES

MPa
%
Mpa
gr/m²·d
ml/m²·d·bar
%

VALUE

22.9 ± 0.2
580 ± 10
142 ± 2
< 0.70
< 0.70
0.02

PROCEDURE

ISO 527
ISO 527
ISO 527
DIN 53122
DIN 53380
ISO 1887

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Issued by QA: Dott. Gobbo

Verified by RDQ: Dott. Maghetti

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