TECHNICAL DATA SHEET

A.18 Rev 02

Cod. **18APN.I**

Product description: container 60 ml, in PP, with red screw cap, with field frosted for identification, individually wrapped, sterile version

Standard packaging:

- single wrap
- carton box of 500 pieces, carton weight 5,5 kg – sell unit
- pallet dim. 1.200x800x2.200h mm of 12.000 pieces, pallet weight 147 kg



Main features

Microbiological status	sterile
Raw material for container	PP
Raw material for cap	HD-PE
Cap color	Red
Capacity (ml)	60
Weight (g)*	8,75

*tolerance ± 1

IVD

CE

IN VITRO DIAGNOSTICAL MEDICAL DEVICE
FOR PROFESSIONAL USE ONLY
THIS PRODUCT FULFILS THE REQUIREMENTS OF DIRECTIVE 98/79/CE

MANUFACTURER DEFINITION:

Anicrin S.r.l.
Via Moglianese, 44/L
I-30037 SCORZÉ (VE)
p: +39 041 445660
e: info@anicrin.com
www.anicrin.com

RACCOMANDATION FOR USE (informative only)

- Use only for laboratory analysis
- Use gloves: contamination risk if contents leak
- Do not use after expiry date
- Do not change the intended use of the product
- Keep out of reach children
- Store in dry place and far from the direct light
- Disposal: use the appropriate PPE (personal protective equipment) and dispose according to current legislation

INTENDED USE

Device containers are disposable labware intended to be used in laboratory to contain biological liquids for in vitro diagnostic analysis.
FOR IN VITRO USE ONLY.
The use and the manipulation of the devices are **reserved to the medical and technical staff** with the necessary professional qualification.

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CLASSIFICATION

Complying with the Directive 98/79/CE concerning medical-diagnostic in vitro devices receipt in Italy with D.L. n°332, G.U.R.I. n. 269 del 17 November 2000, Anicrin S.r.l. defines all the components of the above product family as medical-diagnostic in vitro devices and classifies them as "Other medical-diagnostic in vitro devices" to be made compliant with Annex III of the Directive. On demand, the Declaration of Conformity to the Directive 98/79/CE is available at the Quality Department Anicrin S.r.l.

MATERIALS

Materials used to produce in vitro labware devices are selected on the base of the properties indicated for the individual destination use.
Devices are made by:
containers in polypropylene (PP)
cap in polyethylene (HD-PE)
The **polypropylene** is a translucid, light, resistant to autoclaving. It has excellent characteristics of chemical resistance (to ambient temperature it does not come melted from some dissolvent).
The **polyethylene** is a light, unbreakable and opaque material, very good chemical resistance to solvents. It is utilized to produce stoppers and Pasteur pipettes.

STERILIZATION

For sterile products Beta treatment statements are available for each specific batch (on demand).
VALIDATED TREATMENT.
All products sell as "STERILE" are treated in accordance with UNI EN 556 and UNI EN ISO 11137 standards.

PACKAGING MATERIALS

Coextruded film coex: transparent, neutral material, suitable for the packaging of medical and food products.
All the materials used for the packaging are non-polluting products, fit to the intended use.

Symbols meaning on the packaging:

	do not reuse		batch code
	in vitro diagnostical medical device		use by
	this product fulfils the requirements of Dir. 98/79/CE		manifacturer
	caution		temperature limitation
	sterilized using irradiation		

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anicrin srl
via Moglianese, 44/L
30037 Scorzè (VE) Italy
Tel +39 041 445 660
Fax +39 041 447 990
info@anicrin.com
www.anicrin.com
A brand of i'M