

<i>Code</i>	<i>Description</i>	
21890	Polypropylene container sterile , labeled graduation, screw cap and collection device for urine collection with vacuum tube.	
<i><u>Size and details:</u></i>		
Translucent container		Standard yellow cap
Diameter: Diameter base: Height: Volume: Graduation: Indication minimum level: Indication maximum level: Canula (20G):		48 mm 39 mm 64 mm 60 ml 10-20-30-40-50-60 ml 50 ML 60 ML The canula is in stainless steel AISI 304 siliconized with single tip with protective rubber colored in no glare grey.





The new **Container 60 ml** with collection device for the safety collection of the urine with vacuum tubes it is an innovative method because:

- There are less volume for the storage and the transport from the warehouse to the users in the hospitals.
- There are less volumes in the Transport of the samples from collection points to the labs.
- There are less costs for the hospitals for getting rid of the waste potentially infected (After the use are the waste potentially infected : CER 18 01 03* waste that must be collected and cleared out with caution in order to avoid infections).
- It respect the environment because there is a lower consumption of plastic raw material and it reduce the transport costs

The new **Container 60 ml** with collection device for collection with vacuum tubes guarantee to fill 4 tubes of 10/11 ml.

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<u>Nominal validity</u>		
3 years from the date of production		
<u>Label:</u>		
White self-adhesive, identified and with protection, it contains : name and address of the manufacturer, reference, lot number, Sterile R interior, expiring date, CE mark, warnings and symbols for use. Applied on the cap it sales the hole which contains the adapter for the collection of the samples with a vacuum tube with predetermined vacuum		
<u>Sterility:</u>		
By irradiation as per directives: UNI EN 556-1 Requirements for the medical device that indicates that the product is sterile. UNI EN ISO 11137-1:2006 Sterilization of the health products – Irradiation part 1- UNI EN ISO 11737-2 Microbiology method – Test of sterility made during the validation of the process of sterilization.		
<u>Packaging:</u>		
<i>Single wrapped</i>	<i>Middle packaging</i>	<i>Inner packaging inseparable for sales</i>
=====	Transparent bag	Boxes of 500 pcs – labels applied with : CE, REF, quantity, description, lot, exp date, manufacturer, indication of sterility, international symbols, bar code
<u>Destination of use :</u>		
For urine collection and subsequent chemical analysis and determination of urine-culture and sedimentation. <u>This product has to be used by professionally qualified personnel.</u> <u>In case you are going to use the container for collection of more than two tubes, we suggest to lightly unscrewed the cap.</u>		
<u>Container material:</u>		<u>Cap material:</u>
POLIPROPILENE – non toxic material – translucent and shock proof, flexible, it is a barrier against the humidity, resistant to oils and solvents, and to temperature up to 130 °C – for medical use is common for tubes and containers.		POLYIETYLENE – non toxic material, translucent, extremely shock proof.
<u>System applied during manufacturing and reference standards:</u>		
UNI EN ISO 9001:2015 certificate ICIM n. 4264/5 issued by ICIM S.p.a. UNI CEI EN ISO 13485:2016 certificate ICIM n. 4265/5 issued by ICIM S.p.a. CE: quality guarantee system through issue of Declaration of Conformity CE after preparation of technical files as per Directive CE 98/79/CE (D.L. 08/09/2000 N.332) available to the competent		
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authorities

UNI EN 928 Diagnostic in vitro – Guides of directions EN29001 ed EN46001 and EN 29002 and EN46002 for medical devices for in vitro diagnosis.

EN 375 Diagnostic systems in vitro – Requirements for the labels and the information about the product concerning the reagents related to the reagents for diagnostics in vitro for professional use.

UNI CEI EN ISO 15223-1:2012 Symbols to be used in the labels of the medical device, during the labelling process and in the information that must be supplied (ex UNI CEI EN 980:2009)

UNI EN 14971 Application of the management of the risks of the medical device.

Disposal method:

Before the use the products have to be consider not hazardous material as D.Lgs. 156/06 e s.m.i.

After the use become waste potentially infected that have to collect and disposed applying all particular precautions to avoid infections: CER 18 01 03*.

Raw material certifications:

All raw materials used are non-toxic, food and medical certified, as per European and FDA (USA) directives.

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