Code	***Description***	
21890	**Polypropylene container sterile, labeled graduation, screw cap and collection device for urine collection with vacuum tube.**	

Size and details:

Translucent container	**Standard yellow cap**

Diameter:	**48 mm**
Diameter base:	**39 mm**
Height:	**64 mm**
Volume:	**60 ml**
Graduation:	**10-20-30-40-50-60 ml**
Indication minimum level:	**50 ML**
Indication maximum level:	**60 ML**
Canula (20G):	**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.

Nominal validity

3 years from the date of production

Label:

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

Sterility:

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.

Packaging:

Single wrapped	Middle packaging	Inner packaging inseparable for sales
====	Transparent bag	Boxes of 500 pcs – labels applied with : CE, REF, quantity, description, lot, exp date, manufacturer, indication of sterility, international symbols, bar code

Destination of use :

For urine collection and subsequent chemical analysis and determination of urine-culture and sedimentation.

This product has to be used by professionally qualified personnel.

In case you are going to use the container for collection of more than two tubes, we suggest to lightly unscrewed the cap.

Container material:	Cap material:
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.

System applied during manufacturing and reference standards:

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

authorities

UNI EN 928 Diaggnostic 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.