CND code: W05010202

PRODUCT DESCRIPTION

Cylindrical sterile PET plastic collection tube (polyethylene terephthalate) Ø 16x100 mm for urine without additive
Vacuum: 9 ml



Foto codice 14930

Dimensions and specifications

Tubes in PET (polyethylene terephthalate) transparent, shockproof.

Material:	polyethylene terephthalate;
Diameter:	16 mm external size of the tube;
Height:	100 mm

Stopper and re-positionable Safety Cap

Butyl rubber stopper, black.	Safety cap against aerosol, in polyethylene. Safety grip surface of 20 mm, to protect end-user

Predetermined vacuum : 9 ml

SHELF LIFE: 18 (eighteen) months from manufacturing date

REFERENCE CODES AND CAP COLOURS

REFERENCE CODE	CAP IMAGE	REFERENCE CODE	CAP IMAGE	REFERENCE CODE	CAP IMAGE
14930 YELLOW		**149400** RED		**14935** RUSTY	
149450 BLACK		**149420** GREEN		**149280** BLU	
149457 ORANGE		**14936** BEIGE		**149484** LAVENDER	
149495 LIGHT BLU		**149466** BROWN		**149486** PINK	

OTHER COLOURS ARE ALSO AVAILABLE, BASED ON THE FOLLOWING TABLE:

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ADDITIVE

NONE

Destination of use:

Usable for biological liquids sample collection.
This product has to be used by professionally qualified personnel.

RECOMENDED USE

Mixing indications: Immediately after collection, gently invert the sample 6 – 8 times;
Minimum time before centrifugation: none
Maximum time before centrifugation: at 2-8 °C within 24 hours
Centrifugation speed: 400 g for 5 minutes
Conversion formula: $g=1{,}118x10^{-5}x\ R\ x\ S^2$ (g = relative centrifugation force, R = rotating radius expressed in cm, S = centrifugation RPM) or consult the nomograph on the last page of the technical sheet, to obtain the speed in RPM.
SAMPLE PRESERVATION: after the centrifugation see the following table:

Storage temperatures	Up to 24 °C	at 2-4 °C
Maximum preservation time	≤ 2 hours	≤24 hours

STORAGE AND PRESERVATION

Storage and preservation of the tubes for long periods have to be at a temperature between +5 and +25°C, in dry place. Tubes have to be stored in vertical position with cap on upper side as indicated on each case

TUBE LABEL

Paper label for specific medical use – size 40x20 mm, printed in 3 colors. Label bearing: company name, REF code, additive, lot and expiry, simbology (Sterile R, IVD, CE and disposable), level, cap colour identification, volume of draw, manufacturer.

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PACKAGING

RACK	INNER BOX	SHIPPING CASE
Plastic 50 places rack	**100 pcs (2 racks of 50 pcs)** Each box is printed with: brand name , manufacturer name and address, size, CE mark, sterilization mark, storage and user's directions, origin and single use indication and number of pieces contained in one box. Each box is labeled with a multilingual sealing label, and an additional label with code, cap color, description, drawing volume, lot and expiry (year and month). Each box contain the instruction for use for the tubes.	**1000 pcs (10 boxes of 100 pcs)** Each box is printed with: manufacturer name and address, size of tubes, CE mark, sterilization, storage and user's directions, number of pcs inside of the box. Each box is labeled with manufacturer named and address, multilingual description, brand name "Vacutest plast", CE mark, symbols and relative CE directive, description, size and volume, ref, single use, origin and storage indications, manufacturing and expiry dates, lot and quantity, operator initials and day, cap color, bar code, description in multilingual, Sterilization indication and sterilization sticker.

SIZE OF PACKAGING

Weight 11,1 Kg – Volume 0,044 m³

STERILIZATION:

By irradiation as per directives:
UNI EN 556-1 requirements for sterile medical devices,
UNI EN ISO 11737-2 microbiological method- sterility tests made during the validation of a sterilization process .
UNI EN ISO 11137-1: 2006 sterilization of sanitary products- radiation- Part 1

COMPATIBILITY WITH ANALYTICAL INSTRUMENTS :

No incompatibility with instruments actually present in the market have been reported.
The users must check the compatibility of the external tubes sizes with the sizes requested by the instrument in use in the specific laboratory.

DISPOSAL METHODS :

Before use the tubes have to be considered not hazardous material to be disposed according to Italian law 156/06 and following amendments.
After use, they become potentially infected waste which have to be collected and disposed applying all particular cares to avoid infections: CER 18 01 03.

RAW MATERIAL CERTIFICATIONS:

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

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QUALITY SYSTEM APPLIED DURING MANUFACTURING AND REFERENCE STANDARDS

UNI EN ISO 9001:2015, ICIM certificate no. 4264/5/D issued by ICIM S.p.a. current issue;
UNI EN ISO 13485:2016, ICIM certificate no. 4265/5/D issued by ICIM S.p.a. current issue.

CE: quality guarantee system through the CE Declaration of Conformity issue after preparation of technical files available for competent authorities, and according to CE 98/79/CE Directive (Italian legislative decree 08/09/2000 No.332) .

EN 375 In Vitro Diagnostic Devices – Labels requirements and products information related to the used reagents for IVD products for professional use.

UNI CEI EN ISO 15223-1:2012 symbols to be used on medical devices labels (ex UNI CEI EN 980:2009)

UNI EN 1041 Information given by the manufacturer with medical devices.

UNI EN 14971 – Risk management application on medical devices.

UNI EN 14820 and ISO 6710 – disposable containers for venous blood collection.

NOMOGRAPH

