

Vacutest Kima S.r.l. Via dell'Industria, 12 35020 Arzergrande (PD) Technical Sheet		CODICE 149425	PAGINA 1 DI 4
		REVISIONE 2	DATA 01/02/2016

CND CODE: W05010202

REFERENCE	PRODUCT DESCRIPTION	
149425	Cylindrical sterile PET plastic tube (polyethylene terephthalate) Ø 13x100 mm without additive Vacuum: 6 ml	
<u>Dimensions and specifications:</u>		
Tubes in PET (polyethylene terephthalate) transparent, shockproof.		
Material: Diameter: Height:	polyethylene terephthalate; 13 mm external size of the tube; 100 mm	
<u>Stopper and re-positionable Safety Cap</u>		
Butyl rubber stopper, pierceable.	Safety cap against aerosol, in polyethylene Safety grip surface of 20 mm, to protect end-user. It works as a protection for the operator.	
<u>COLOUR OF THE CAPS IN ORDER TO IDENTIFY THE TUBE:</u> WHITE		
<u>Predetermined vacuum: 6 ml</u>		
<u>SHELF LIFE: 18 (eighteen) months from manufacturing date</u>		
<u>ADDITIVE:</u>		
NONE		
<u>Destination of use:</u>		
Usable for biological liquids (different from blood) sample collection in a sterilized method.		
<u>This product has to be used by professionally qualified operators.</u>		
<u>STORAGE AND PRESERVATION</u>		
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.		
<u>TUBE LABEL</u>		
Adhesive paper label for specific medical use – size 40x20 mm, printed in 3 colours. Label bearing: brand name, REF code, additive, volume of draw, lot and expiry date, symbols (Sterile R, IVD, CE and single use), level, cap color identification, , manufacturer name.		
<u>PACKAGING</u>		





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RACK	INNER BOX	SHIPPING CASE
Plastic 50 places rack	100 pcs (2 racks of 50 pcs) Each box is printed with: brand name "Vacutest Plast", manufacturer name and address, size, CE mark, sterilization, storage and user's directions, origin and single use indication. 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: brand name "Vacutest Plast", 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 8,9 Kg – Volume 0,020 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 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.

QUALITY SYSTEM APPLIED DURING MANUFACTURING AND REFERENCE STANDARDS

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

UNI CEI EN ISO 15223-1 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

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