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ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4265/4/D**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

VACUTEST KIMA S.r.l.

Sede / *Head office*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Uffici direzionali e amministrativi
Unità Operative / *Operative Units*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.
Via Leonardo Da Vinci, 22 – 35028 Piove di Sacco (PD)
Uffici commerciali e magazzino.

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

FEDERAZIONE CISQ
www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

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VACUTEST® kima

www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *"Dispositivi Medico-Diagnostici In Vitro" e s.m.i.*
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante / *manufacturer*: ***VACUTEST KIMA S.r.l. - articoli per laboratori analisi disposable labware***

indirizzo / *address*: ***Via dell'Industria, 12 35020 Arzergrande (PD) - Italia***

telefono / *phone* **+39-049-9720624** fax / *fax* **+39-049-9720182** posta elettronica / *e-mail* **info@vacutestkima.it**

identificazione dei prodotti / *product identification*:

Sistema di prelievo di sangue e altri liquidi biologici mediante provette con vuoto predeterminato in plastica "VACUTEST KIMA".

"VACUTEST KIMA" vacuum blood and biological liquids collection tubes in plastic.

nome commerciale / *brand name*: **"VACUTEST KIMA"**

classificazione dei prodotti / *product classification*: **dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.**
devices other then those mentioned in Annex II of the Directive 98/79/EC as amended

Si dichiara
sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i."*Dispositivi Medico–Diagnostici In Vitro"*.
Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare
under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".
All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data / *place and date*: **Arzergrande, 20/02/2020**

firma / *signature*: **Assicuratore Qualità / Quality Manager**
Giovanni Chiarin

CND CODE: W050101010201

CODE	**PRODUCT DESCRIPTION**	
13060	Sterile PET vacuum tube Ø 16x100 mm with K_3EDTA Drawing: 9 ml	

Dimensions and specifications:

Tubes in Polyethylene terephthalate (PET), transparent, shockproof.

Material:	Polyethylene terephthalate
Diameter:	16 mm (external tube size)
Height:	100 mm

Stopper and repositionable Safety Cap

Pierceable butyl rubber stopper	PE safety cap against aerosol. Safety grip surface of 20 mm, to protect operators.

VACUUM: 9 ml

SHELF LIFE: 18 (eighteen) months from manufacturing date

SAFETY CAP TUBE COLOUR IDENTIFICATION:

LAVENDER

ADDITIVE

K_3EDTA

Tripotassic salt of ethylenediaminetetraacetic acid.
Salt coating corresponding to 1,8 mg/ml of blood ca.

DESTINATION OF USE

It is used for the blood samples collection for following hemochrome tests.
Immediately after the blood collection, the tubes shall be inserted in a rotator to keep the blood mixed with slow movements.

Tubes could be used for following clinical tests on plasma. In that case, after the collection, shake the tubes slowly at least 6-8 times and then centrifuge them, following the indications written on "recommended use".

This product has to be used by skilled personnel.

RECOMMENDED USE

Mixing indications: Immediately after blood collection, gently invert the sample 6 – 8 times;
Centrifugation: none;

Sample preservation:

Storage temperatures	Up to 24 °C	at 2-4 °C
Maximum preservation time	6 hours	≤ 24 hours

CND CODE: W050101010201

BEFORE PROCEEDING WITH HEMATOLOGIC TESTS MIX CAREFULLY

TO OBTAIN PLASMA: centrifuge at 1300g for 10 minutes at 20-25 °C.
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: for plasma separated from blood cells see following table.

Storage temperatures	Up to 24 °C	at 2-4 ° C	≤ -20 °C
Maximum preservation time	≤8 hours	> 8 hours ≤ 48 hours	> 48 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 a dry place. Tubes have to be stored in vertical position with cap upwards as indicated on each case.

TUBE LABEL

Adhesive paper label for specific medical use – size 40x20 mm, printed in 3 colors. 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.

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, 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).	**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. Each box is labeled with manufacturer named and address, brand name "Vacutest plast", CE and IVD 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 with EAN13 indications, description in multilingual, Sterilization indication and sterilization sticker.

SIZE OF PACKAGING

Weight: 11,2 Kg – Volume 0,044 m³

STERILIZATION

CND CODE: W050101010201

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 currently present in the market have been reported. Users must check the compatibility of the external tubes sizes with the sizes requested by the instrument in use in the specific laboratory.

DISPOSAL MODALITY

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, according to the European and FDA (USA) directives.

QUALITY SYSTEM APPLIED DURING MANUFACTURING AND REFERENCE STANDARDS

UNI EN ISO 9001:2008, ICIM certificate no. 4264/3/D issued by ICIM S.p.a. on 18/01/2016;
UNI EN ISO 13485 : 2012 ICIM certificate no. 4265/3/D issued by ICIM S.p.a. on 18/01/2016;

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)

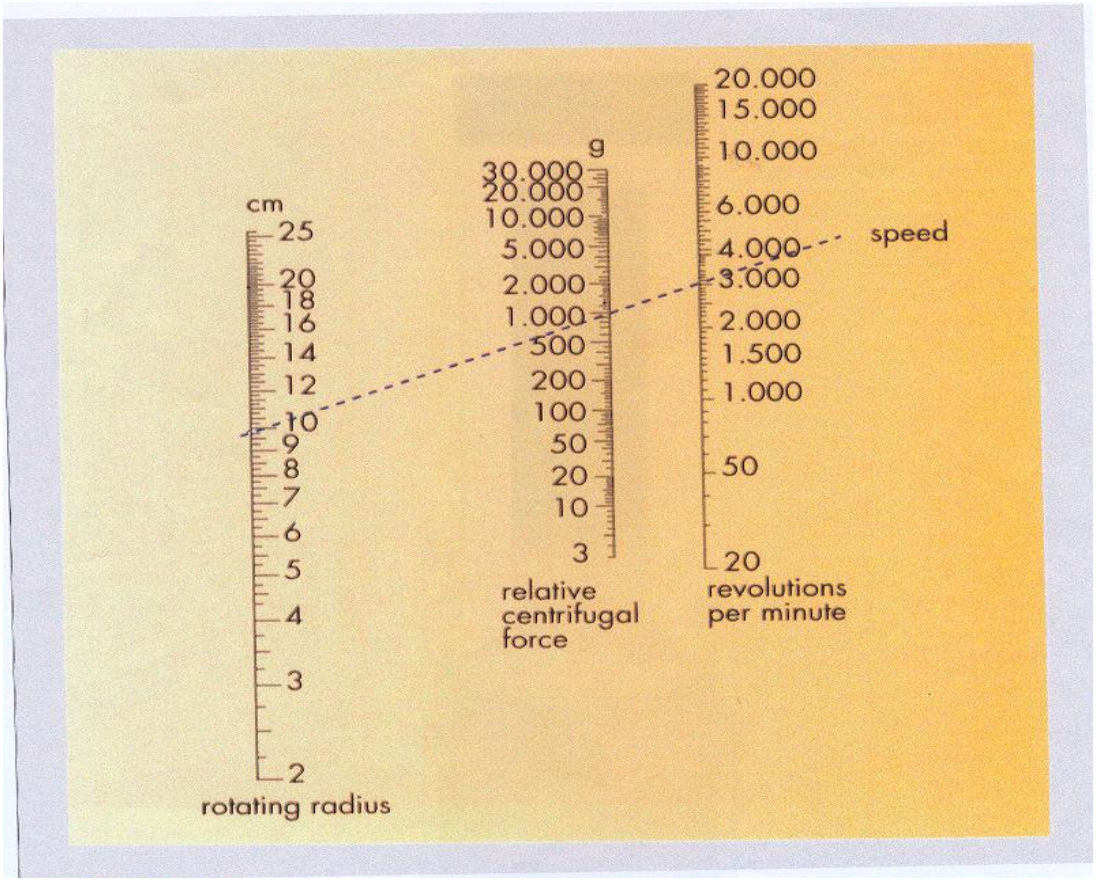
UNI EN 1041 Information given by the manufacturer with medical devices.

UNI EN 14971 – Risk management application on medical devices.

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

CND CODE: W050101010201

NOMOGRAPH



CND CODE: W050101010201

CODE	**PRODUCT DESCRIPTION**	
13040	Sterile PET vacuum tube Ø 13x100 mm with K_3EDTA Drawing: 6 ml	

Dimensions and specifications:

Tubes in Polyethylene terephthalate (PET), transparent, shockproof.

Material: Diameter: Height:	Polyethylene terephthalate 13 mm (external tube size); 100 mm

Stopper and repositionable Safety Cap

Pierceable utyl rubber stopper	PE safety cap against splashes and aerosol. Safety grip surface of 20 mm, to protect operators..

VACUUM: 6 ml

SHELF LIFE: 18 (eighteen) months from manufacturing date

REFERENCE CODES AND CAP COLOURS

REFERENCE CODES	*CAP COLOR*	CAP IMAGE
13040	**LAVENDER**	
13044	**TRANSLUCENT LAVENDER**	

ADDITIVE

K_3EDTA

Tripotassic salt of ethylenediaminetetraacetic acid.
Salt coating corresponding to 1,8 mg/ml of blood ca.

DESTINATION OF USE

It is used for the blood samples collection for following hemochrome tests.
Immediately after the blood collection, the tubes shall be inserted in a rotator to keep the blood mixed with slow movements.

Tubes could be used for following clinical tests on plasma. In that case, after the collection, shake the tubes slowly at least 6-8 times and then centrifuge them, following the indications written on "recommended use".

This product has to be used by skilled personnel.

RECOMMENDED USE

CND CODE: W050101010201

Mixing indications: Immediately after blood collection, gently invert the sample 6 – 8 times;
Centrifugation: none;

Sample preservation:

Storage temperatures	Up to 24 °C	at 2-4 °C
Maximum preservation time	6 hours	≤ 24 hours

BEFORE PROCEEDING WITH HEMATOLOGIC TESTS MIX CAREFULLY

TO OBTAIN PLASMA: centrifuge at 1300g for 10 minutes at 20-25 °C.
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.

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TUBE LABEL

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PACKAGING

RACK	INNER BOX	SHIPPING CASE

CND CODE: W050101010201

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SIZE OF PACKAGING

Weight: 8,9 Kg – Volume 0,036 m³

STERILIZATION

By irradiation as per directives:

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UNI EN ISO 11737-2 microbiological method- sterility tests made during the validation of a sterilization process ,
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NOMOGRAPH