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 PLAST".**

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

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

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, 17/02/2021**

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

Digitally signed by Ceaicovschi Tudor
Date: 2023.11.06 15:12:00 EET
Reason: MoldSign Signature
Location: Moldova

BUFFERED SODIUM CITRATE TUBES
PROVETTE CON SODIO CITRATO TAMPONATO

STERILE R

CODE *codice*	SIZE *dimensioni*	DESCRIPTION *descrizione*	DRAWING *aspirazione*	VOLUME *volume*	COLOUR *colore*	SHELF-LIFE *scadenza*	PACKAGING *confezion.*
14074	13 x 75 mm **(IN)**	Sodium citrate 3,2% *Sodio citrato 3,2%*	1,8 ml	2 ml (1,8 ml+0,2 ml)	Translucent light blue *Azzurro trasparente*	12 months *mesi*	100 / 1000
140740	13 x 75 mm **(IN)**	Sodium citrate 3,2% *Sodio citrato 3,2%*	1,8 ml	2 ml (1,8 ml+0,2 ml)	Light blue *Azzurro*	12 months *mesi*	100 / 1000
14010	13 x 75 mm **(IN)**	Sodium citrate 3,8% *Sodio citrato 3,8%*	1,8 ml	2 ml (1,8 ml+0,2 ml)	Translucent light blue *Azzurro trasparente*	12 months *mesi*	100 / 1000
140100	13 x 75 mm **(IN)**	Sodium citrate 3,8% *Sodio citrato 3,8%*	1,8 ml	2 ml (1,8 ml+0,2 ml)	Light blue *Azzurro*	12 months *mesi*	100 / 1000
14084	13 x 75 mm **(IN)**	Sodium citrate 3,2% *Sodio citrato 3,2%*	2,25 ml	2,5 ml (2,25 ml+0,25 ml)	Translucent light blue *Azzurro trasparente*	12 months *mesi*	100 / 1000
140840	13 x 75 mm **(IN)**	Sodium citrate 3,2% *Sodio citrato 3,2%*	2,25 ml	2,5 ml (2,25 ml+0,25 ml)	Light blue *Azzurro*	12 months *mesi*	100 / 1000
14020	13 x 75 mm **(IN)**	Sodium citrate 3,8% *Sodio citrato 3,8%*	2,25 ml	2,5 ml (2,25 ml+0,25 ml)	Translucent light blue *Azzurro trasparente*	12 months *mesi*	100 / 1000
140200	13 x 75 mm **(IN)**	Sodium citrate 3,8% *Sodio citrato 3,8%*	2,25 ml	2,5 ml (2,25 ml+0,25 ml)	Light blue *Azzurro*	12 months *mesi*	100 / 1000
143630	13 x 75 mm **(GR)**	Sodium citrate 3,2% *Sodio citrato 3,2%*	2,7 ml	3 ml (2,7 ml+0,3 ml)	Light blue *Azzurro*	9 months *mesi*	100 / 1000
14365	13 x 75 mm **(GR)**	Sodium citrate 3,2% *Sodio citrato 3,2%*	3,15 ml	3,5 ml (3,15 ml+0,35 ml)	Translucent light blue *Azzurro trasparente*	9 months *mesi*	100 / 1000
143650	13 x 75 mm **(GR)**	Sodium citrate 3,2% *Sodio citrato 3,2%*	3,15 ml	3,5 ml (3,15 ml+0,35 ml)	Light blue *Azzurro*	9 months *mesi*	100 / 1000
143656	13 x 75 mm **(GR)**	Sodium citrate 3,2% *Sodio citrato 3,2%*	3,15 ml	3,5 ml (3,15 ml+0,35 ml)	Electric blue *Blu elettrico*	9 months *mesi*	100 / 1000
14315	13 x 75 mm **(GR)**	Sodium citrate 3,8% *Sodio citrato 3,8%*	3,15 ml	3,5 ml (3,15 ml+0,35 ml)	Translucent light blue *Azzurro trasparente*	9 months *mesi*	100 / 1000
143150	13 x 75 mm **(GR)**	Sodium citrate 3,8% *Sodio citrato 3,8%*	3,15 ml	3,5 ml (3,15 ml+0,35 ml)	Light blue *Azzurro*	9 months *mesi*	100 / 1000
14574	13 x 75 mm	Sodium citrate 3,2% *Sodio citrato 3,2%*	3,6 ml	4 ml (3,6 ml+0,4 ml)	Translucent light blue *Azzurro trasparente*	6 months *mesi*	100 / 1000

GEL AND CLOT ACTIVATOR TUBES

PROVETTE CON GEL E ATTIVATORE DELLA COAGULAZIONE

STERILE R

CODE *codice*	SIZE *dimensioni*	DESCRIPTION *descrizione*	DRAWING *aspirazione*	COLOUR *colore*	SHELF-LIFE *scadenza*	PACKAGING *confezion.*
10006	13 x 75 mm **IN**	Gel+Clot activator *Gel+Attivatore della coagulazione*	2 ml	Red *Rosso*	18 months *mesi*	100 / 500
100071	13 x 75 mm **IN**	Gel+Clot activator *Gel+Attivatore della coagulazione*	2 ml	Yellow *Giallo*	18 months *mesi*	100 / 500
10008	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	2 ml	Red *Rosso*	18 months *mesi*	100 / 500
10010	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	Red *Rosso*	18 months *mesi*	100 / 500
10174	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	Gold *Giallo ocra*	18 months *mesi*	100 / 500
10108	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	Yellow *Giallo*	18 months *mesi*	100 / 500
10303	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	Rusty *Terra di Siena*	18 months *mesi*	100 / 500
10227	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	Electric blue *Blu elettrico*	18 months *mesi*	100 / 500
10305	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	Translucent *Trasparente*	18 months *mesi*	100 / 500
10092	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	Translucent red *Rosso trasparente*	18 months *mesi*	100 / 500
10342	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	Orange *Arancio*	18 months *mesi*	100 / 500
10204	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	Light blue *Azzurro*	18 months *mesi*	100 / 500
10148	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	Dark blue *Blu*	18 months *mesi*	100 / 500
10142	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	White *Bianco*	18 months *mesi*	100 / 500
10102	13 x 75 mm	Gel+Clot activator *Gel+Attivatore della coagulazione*	3,5 ml	Beige *Beige*	18 months *mesi*	100 / 500

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60150763 0001

Report No.: 21234760 013

Manufacturer:

KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products:

- Cannulas for blood collection
- MBU Capillaries
(see attachment for details)

Replaces certificate, Registration No.: HD 60105393 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Effective Date: 2020-10-07

Date: 2020-10-07

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60150763 0001
Report No.: 21234760 013

Manufacturer: KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products included:

- Cannulas for blood collection

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- MBU Capillaries

Notified Body

Date: 2020-10-07

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer:

Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets,
Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Products: Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Suction Connecting Tubes with Yankauer, Sterile Latex Surgical Gloves, Disposable Surgical Blades & Scalpels With Plastic Handle, Sterile Blood Lancets, Disposable Syringes, Disposable Infusion Sets, Disposable Transfusion Sets, Intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Disposable Tracheal Tubes (Standard & Reinforced), Disposable Oxygen Masks, Non-Rebreathing Masks, Aerosol Masks, Closed Suction Catheters, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Wound Drainage System with and without Trocars, Needle Free Connectors, Digital Thermometers, Humidifier Jar (Bubble Humidifier Jar), Enteral Feeding Sets (Bag);
Aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Disposable

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

BOEN HEALTHCARE CO., LTD
Unit 602, International Center, No.535, Shenxu Road,
Suzhou, 215021, Jiangsu, China

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Plastic Test Tube

der Klasse: /
of class: /
de la classe: /
di classe:

Common/Others IVD
(Devices of NOT Annex II and NOT self-test)

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
(IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d’évaluation de la conformité: /
Procedura di valutazione della conformità:

Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /
EG Annex III (expect point 6) of IVDD 98/79/EC
Annexe III (sauf le point 6) de l'IVDD 98/79 / CE
Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE

Registrier-Nr.: /
Registration No.: /
N°d’enregistrement: /
Numero di registrazione:

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 2022.01.01

General Manager

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione