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:

Filter Pipette Tips
UMDNS-Code: [16822]

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

Other

(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:

Annex II and III of the 98/79/EC in Vitro Diagnostic Medical Devices Directive

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

Digitally signed by Ceaicovschi Tudor
Date: 2022.10.28 15:57:23 EEST
Reason: MoldSign Signature
Location: Moldova

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

CE

Suzhou, 2020.05.01

General Manager

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

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

Filtered Pipettes Tips

Filter pipette tips are used for protection against contamination.
Pipette tips with filter barrier protects pipettors and samples from contamination.
RNase, DNase and Pyrogen Free.
Filtered tips,Filter Tips Pipette, universal and fit most popular brands of pipettors.

Sterile pipette tips.
PP Material,clear color.
Volume:10ul-1000ul.
Package Style: Bulked: 1000tips/bag, 10bags/ctn
Racked: 96tips/rack, 10racks/pk, 50racks/ctn

Cat No.	Description	Qty/Case(pcs)
640401	Racked filter short tips,96tips/rack,sterile,10ul	4800
640402	Racked filter long tips,96tips/rack,sterile,10ul	4800
640403	Racked filter tips,96tips/rack,sterile,20ul	4800
640404	Racked filter tips,96tips/rack,sterile,50ul	4800
640405	Racked filter tips,96tips/rack,sterile,100ul	4800
640406	Racked filter tips,96tips/rack,sterile,200ul	4800
640407	Racked filter tips,96tips/rack,sterile,1000ul	4800
640408	Racked filter tips,96tips/rack,sterile,1250ul	4800
640409	Bulked filter short tips,1000tips/bag,sterile,10ul	10000
640410	Bulked filter long tips,1000tips/bag,sterile,10ul	10000
640411	Bulked filter tips,1000tips/bag,sterile,20ul	10000
640412	Bulked filter tips,1000tips/bag,sterile,50ul	10000
640413	Bulked filter tips,1000tips/bag,sterile,100ul	10000
640414	Bulked filter tips,1000tips/bag,sterile,200ul	10000
640415	Bulked filter tips,1000tips/bag,sterile,1000ul	10000
640416	Bulked filter tips,1000tips/bag,sterile,1250ul	10000

ADD: UNIT 602, YOUNGOR INTERNATIONAL CENTER, SHENXU ROAD, SUZHOU INDUSTRIAL PARK, CHINA
TEL: 86 512 62572107 FAX: 86 512 62922078 EMAIL: SALES@BOENMEDICAL.COM

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:	**Vacuum Blood Collection 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, 201.05.26

General Manager

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

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

Vacuum Blood Collection Tube, EDTA Tube

Vacuum Blood Collection Tube, EDTA Tube

Meterial: PET, Glass

Color: Violet

Cat. No.	Specification	Volume	Additive	Qty/case (Glass)	Qty/case (PET)
630801	13×75mm	1ml	EDTAK2	1800	1800
630802	13×75mm	2ml	EDTAK2	1800	1800
630803	13×75mm	3ml	EDTAK2	1800	1800
630804	13×75mm	4ml	EDTAK2	1800	1800
630805	13×75mm	5ml	EDTAK2	1800	1800
630806	13×100mm	5ml	EDTAK2	1200	1200
630807	13×100mm	6ml	EDTAK2	1200	1200
630808	13×100mm	7ml	EDTAK2	1200	1200
630809	16×100mm	10ml	EDTAK2	900	900
630901	13×75mm	1ml	EDTAK3	1800	1800
630902	13×75mm	2ml	EDTAK3	1800	1800
630903	13×75mm	3ml	EDTAK3	1800	1800
630904	13×75mm	4ml	EDTAK3	1800	1800
630905	13×75mm	5ml	EDTAK3	1800	1800
630906	13×100mm	5ml	EDTAK3	1200	1200
630907	13×100mm	6ml	EDTAK3	1200	1200
630908	13×100mm	7ml	EDTAK3	1200	1200
630909	16×100mm	10ml	EDTAK3	900	900
631001	13×75mm	2ml	EDTANA2	1800	1800
631002	13×100mm	10ml	EDTANA2	1200	1800

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

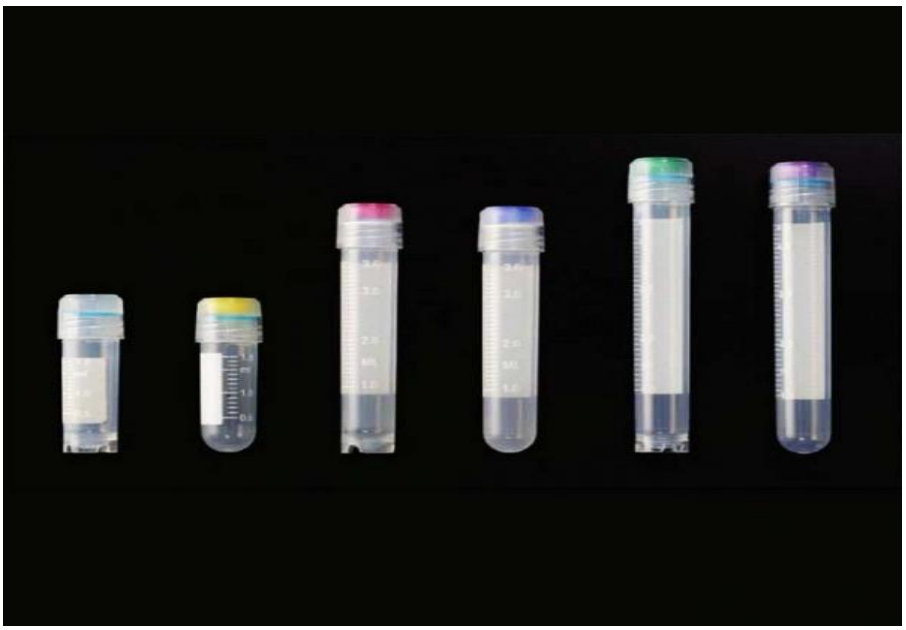
Expiry date: 2024-05-26

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.



Cryovial Tube with External Thread

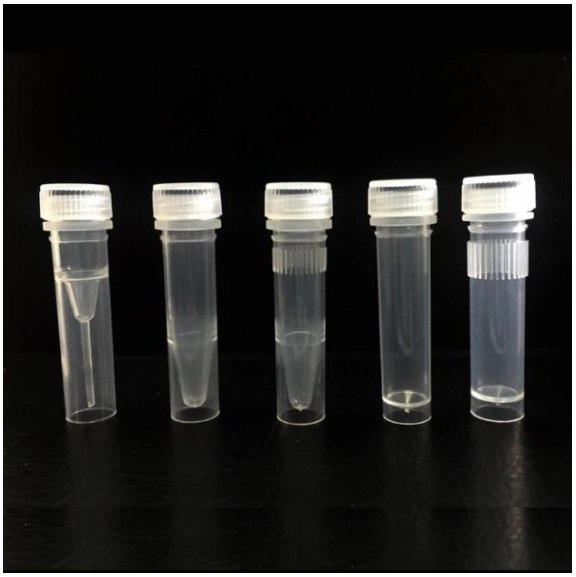
Designed for the storage and transportation of biological specimens,can be used in the liquid phase or liquid nitrogen.
Made of high quality PP material, with large white writing surface for specimen identification.
With printed graduations for accurate measurements.
Can withstand -196℃ to 121℃degrees Celsius temperature.
DNAse, RNAse free and the heat source free.
Round bottom or self-standing bottom can be choose.

Cat No.	Description
661801	External Thread Cryogenic Vial,self-standing bottom,1.0ml
661802	External Thread Cryogenic Vial, round bottom,2.0ml
661803	External Thread Cryogenic Vial, self-standing bottom,2.0ml
661804	External Thread Cryogenic Vial, round bottom,4.0ml
661805	External Thread Cryogenic Vial, self-standing bottom,4.0ml
661806	External Thread Cryogenic Vial, round bottom,5.0ml
661807	External Thread Cryogenic Vial, self-standing bottom,5.0ml

ryogenic Storage Boxes

Cryogenic storage boxes made of high-quality polycarbonate plastic, used in ultralow freezer and liquid nitrogen storage vessels. Can be used in temperatures from -196℃ to +121℃.
Cryo freezer box hold 1.5ml,2.0ml standard cryogenic vials,and microcentrifuge tubes.
25-place,81-place,and 100-place sizes optional.
PC storage boxes with 4 assorted colors: red, yellow, green, and blue

Cat No.	Description	Qty/Case(pcs)
662201	Cryogenic Storage Boxes,25-well	100
662202	Cryogenic Storage Boxes,81-well	100
662203	Cryogenic Storage Boxes,100-well	100



Micro Cryogenic Tube

Micro Cryogenic Tube

Micro Cryogenic Tube made of PP material.Choose tubes in skirted style, natural color, in 0.5mL, 1.5mL and 2mL sizes.

Cat No.	Description	Qty/Case
661601	0.5ml Micro Cryogenic tube, clear, PP	12000
661602	1.5ml Micro Cryogenic tube, clear, PP	10000
661603	1.5ml Micro Cryogenic tube, clear, PP, Skirted	10000
661604	2ml Micro Cryogenic tube, clear, PP	10000
661605	2ml Micro Cryogenic tube, clear, PP, Skirted	10000