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:

Virus specimen collection kit

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:

Digitally signed by Ceaicovschi Tudor
Date: 2022.03.16 09:12:21 EET
Reason: MoldSign Signature
Location: Moldova

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

CE

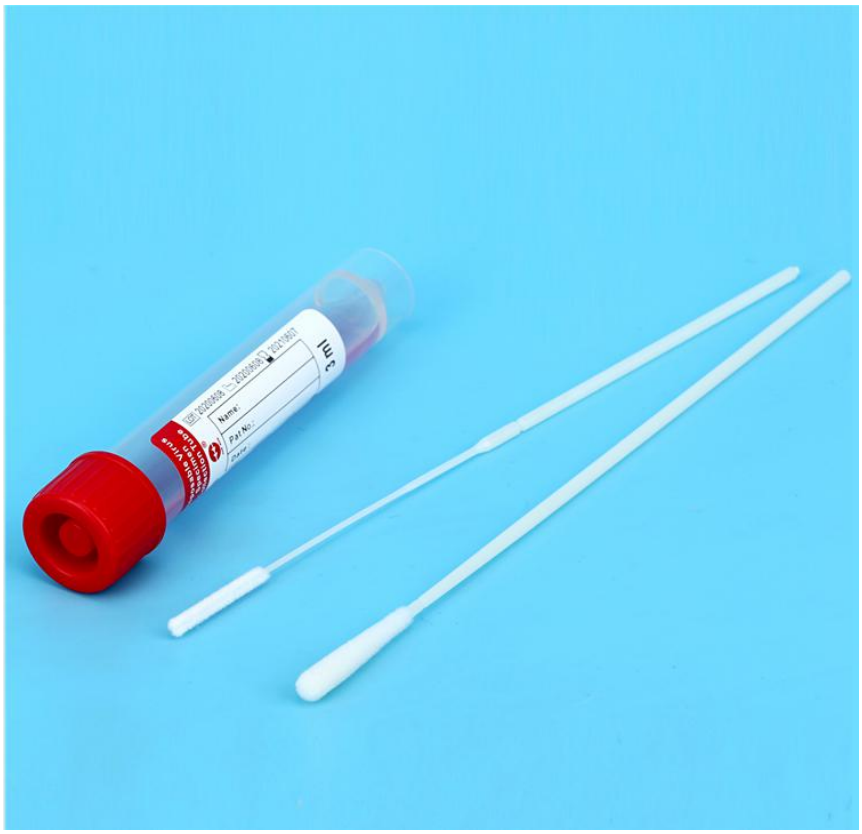
Suzhou, 2021.09.26

General Manager

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

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

SHANDONG CHENGWU MEDICAL PRODUCTS FACTORY



Product Name：Disposable Virus Specimen Collection Tube
Shelf Life：12 months
Store Under：Room Temperature 4-25℃

Product Description:
Virus collection kit is used for collection,transport,maintenance and long term freeze storage of Viruses, such as COVID-19 Virus,Influenza,including H1N1,Chlamydia,Mycoplasma and Ureaplasma specimens.The Virus sampling tube swab kit can be conveniently stored at room temperature.

Sampling tube:
The tube body and tube cap are Sterilized by Gamma Radiation , Non heat source, DNAse and RNAse free. To ensure that the sampling tube itself will not have a toxic effect on the sample. The tube body and cap are made of high-quality medical grade polypropylene material, which is transparent and clean, without deformation at high temperature and high pressure (120 ℃ 15min), and does not become brittle at low temperature (-80 ℃)

Sample Requirements

The collected flock swab samples should be transported at 2°C-8°C and submitted for inspection immediately. Sample transport and storage time should be no later than 72h.

User Manual

1. Mark the sample information on the label before sampling.
2. Collect the specimen with the swab.
a. Nasal swab: gently insert the swab into the nasal cavity for sampling, use another swab to collect another nasal sample in the same way.
b. Throat swab: collect the throat sample.
3. Put the swab into the transport tube contains virus transport medium after sampling.
4. Snap the swab at the break point into the transport tube and screw the cap tightly.
5. It is better o transport the collected samples to the laboratory with ice packs.

Pay Attention

1. When collecting and handling specimens, gloves, protective clothing, goggles and other personal protective equipment shall be worn to avoid splashing, leakage and exposure of potential pathogens.
2. All biohazardous specimens and devices shall be disposed of in accordance with the relevant regulations and procedures and discarded in the designated collection containers.
4. After use, the waste shall be disposed according to the regulations of the hospital or the environmental protection department.
5. Read Instructions for Use on this packing carefully before use,and use it within the validity period.
6. Warming and prevention: it is forbidden to us when package damage, foreign matters, leakage,storage liquid turbidity and expiration date are found.

Kit include: 1pc 10ml sampling tube with 2ML VTM LIQUID or 3ML VTM LIQUID.
1pc Nasal flocked swab
1pc Oral flocked swab
Sterile blister pack.

Cat No.	Description	Qty/Case
611903	Virus collection kit with 2 swab,(1pc nasal swab+1pc oral swab)	300

Manufacturer

Shandong Chengwu Medical Products Factory
Add:Southern End of Huxin Road, Chengwu County, Heze City,Shandong Province P.R. China

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

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REGISTRATION NO. 04720Q10000336

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Shandong Chengwu Medical Products Factory

Registered Address: Southern End of Quancheng Road,Chengwu County,274200 Heze City,Shandong Province,P.R.China

Manufacturing Address: Southern End of Quancheng Road,Chengwu County

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The development,production and service of disposable virus specimen collection tube.

Date of issue: July 13,2020

Date of expiry: July 12,2023

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993