

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

Name und Adresse des Herstellers: / **BOEN HEALTHCARE CO., LTD**
Name and address of the manufacturer: / **Unit 602, International Center, No.535, Shenxu Road,**
Nom et adresse du fabricant: / **Suzhou, 215021, Jiangsu, China**
Nome e indirizzo del fabbricante:

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: / **Filtered Pipette Tips**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
di classe:

(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: / **Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /**
Conformity assessment procedure: / **EG Annex III (expect point 6) of IVDD 98/79/EC**
Procédure d'évaluation de la conformité: / **Annexe III (sauf le point 6) de l'IVDD 98/79 / CE**
Procedura di valutazione della conformità: **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

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

General Manager

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: Bulk: 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	Bulk filter short tips, 1000tips/bag, sterile, 10ul	10000
640410	Bulk filter long tips, 1000tips/bag, sterile, 10ul	10000
640411	Bulk filter tips, 1000tips/bag, sterile, 20ul	10000
640412	Bulk filter tips, 1000tips/bag, sterile, 50ul	10000
640413	Bulk filter tips, 1000tips/bag, sterile, 100ul	10000
640414	Bulk filter tips, 1000tips/bag, sterile, 200ul	10000
640415	Bulk filter tips, 1000tips/bag, sterile, 1000ul	10000
640416	Bulk filter tips, 1000tips/bag, sterile, 1250ul	10000

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Sterile pipette tips.

PP Material, clear color.

Volume: 10ul-1250ul.

Package Style: Bulk: 1000tips/bag, 10bags/ctn

Racked: 96tips/rack, 10racks/pk, 50racks/ctn

Cat No.	Description	Qty/Case(pcs)
640403	Racked filter tips, 96tips/rack, sterile, 1- 20ul	4800
640406	Racked filter tips, 96tips/rack, sterile, 20-200ul	4800
640407	Racked filter tips, 96tips/rack, sterile, 100-1000ul	4800



This is to certify that the Quality Management System of

Jiangsu Benoy Lab Instrument Co., Ltd.

Unified Social Credit Code : 91320903MA1MD4UW3A

Operation Address : No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng City, Jiangsu Province, China

Registered Address : No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng City, Jiangsu Province, China

applicable to

Production and Sales of Non-sterile: Microscope Slides, Cover Glass and Laboratory Plastic (Specimen Container, Test Tube, Tube Stopper, Petri Dish, Pipette Tips, Centrifuge Tube) (Export to the US and EU); Sales of Laboratory Glassware (Glass Test Tube, Beaker, Flask, Reagent Bottle, Measuring Cylinder, Volumetric Flask, Glass Petri Dish, Dropper Pipette, Capillary Tubes, Vacuum Blood Collection Tube, Blood Counting Chamber) and Laboratory Plastic (Transfer Pasteur Pipette, Freezing Tube, Tube Rack, Slides Mailer, Storage Box, Inoculation Loop, Embedding Cassettes) (export to the US and EU)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number

47164

Date:

18 November 2019

Valid Until:

18 November 2022

EAC Code:

14/29





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