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: 2021.04.16 12:07:06 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

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