

BOEN HEALTHCARE CO., LTD

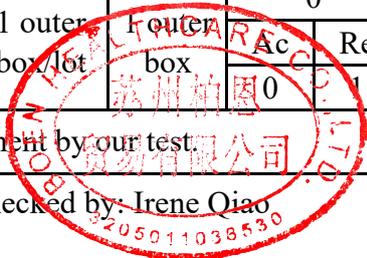
CERTIFICATE OF ANALYSIS

Report No.: GM04-BN24

Product Name: Gilson Pipette Tips		Lot. No.: 20241220					
MFG. Date: 2024-12		EXP. Date: 2029-11					
Raw Material: PP		Specification: 5000µL					
Standard: Enterprise Standard							
Package: 300pcs/bag, 8850pcs/ctn							
Quantity: 8850pcs			Report Date: 2025.01.10				
Test Items	Technical Requirement	Inspection Level	Sample	AQL		Defect Qty	Result
Dimension	L: 100±1mm	5pcs/lot	5pcs	0		0	Pass
				Ac	Re		
				0	1		
Appearance	No burr, black dot, dust, scratch, no oil spot, breakage, shrink color correct, blocking is not permitted	GB/T 2828.1-2003 Normal test level II	800pcs	1.5		0	Pass
				Ac	Re		
				21	22		
Function	Can be assembled with pipettor well	10pcs/lot	10pcs	0		0	Pass
				Ac	Re		
				0	1		
Package	Label and marking should be clear, correct and the label should be on correct location.	1 outer box/lot	1 outer box	0		0	Pass
				Ac	Re		
				0	1		
Conclusion	The product meets all the requirements by our test.						

Inspected by: Leo Sun

Checked by: Irene Qiao



**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: / **Gilson 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:

Suzhou, 201.05.26

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

CE

General Manager

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

