中国国际贸易促进委员会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书
CERTIFICATE

号码 No. 213201A0/000513

兹证明：在所附文件上的苏州柏恩贸易有限公司的印章属实。

THIS IS TO CERTIFY THAT: the seal of BOEN HEALTHCARE CO., LTD. on the annexed DOCUMENT is genuine.

China Council for the Promotion of International Trade

授权签字：

Authorized Signature:

Zou Ruirui

Digitally signed by Granaci Boris
Date: 2021.10.01 14:47:38 EEST
Reason: MoldSign Signature
Location: Moldova

日期：2021年01月15日

(Date: Jan. 15, 2021)

证明书查验网址 Website for verifying the certificate: http://www.rzccpit.com/validate.html

认字第21001356号

兹证明前面文书上中国国际贸易促进委员会商事证明专用章（27）和授权签字人（**邹锐锐**）的签字属实。

中华人民共和国外交部（320）

二〇二一年一月十九日 南京

00599264

Yukarıdaki imza ve mühürün **Jiangsu** Eyaleti Halk Hükümeti Dış İlişkiler Bürosu'na ait olduğu tasdik olunur.

Genel No : 28060805

Özel No : 698

Tarih : 28.01.2021

T.C. ŞANHAY BAŞKONSOLOSLUĞU

S.Doğa ÖLMEZ
Vice Consul

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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**
Name und Adresse des Vertreters der EG: / Name and address of the EC representative: / Nom et adresse du représentant de la CE : / Nome e indirizzo del rappresentante CE:	**Sungo Europe B.V. Olympisch Stadion 24, 10076DE Amsterdam, Netherlands**

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:	**Nasal Oxygen Cannulae [12700], Suction Catheters [17795], Stomach Tubes [14230], Feeding Tubes [14199], Suction Connecting Tubes with Yankauer [14188,16883], Sterile Latex Surgical Gloves [11883], Disposable Surgical Blades & Scalpels with Plastic Handle [12234], Sterile Blood Lancets [10440], Disposable Syringes [13929], Disposable Infusion Sets [17984], Disposable Transfusion Sets [14126], Intravenous Needles for Single Use [12748], Sterile Hypodermic Needles for Single Use [12745], Disposable Tracheal Tubes (Standard & Reinforced) [14085], Disposable Oxygen Masks [12448], Non-Rebreathing Masks [12450], Aerosol Masks [12449], Closed Suction Catheters [16779], Tracheostomy Tubes [14096], Laryngeal Mask Devices [16827], Digital Thermometers [14032], Disposable Air Cushion Face Masks [12453], Oropharyngeal Airways [10059], Venturi Masks [12452], Self-destruction Safety Syringes [13940], Blood Collecting Needles [12736], Foley Catheters [10720], Disposable Acupuncture Needles [12730], Disposable Breathing Circuits [15562], Three-way Stopcocks (with Extension Tube) [13803], Nelaton Catheters [10762], Insulin Needles for Single Use [15781], Humidifier Jar (Bubble Humidifier Jar) [12047], Enteral Feeding Set (Bag) [11675], Wound Drainage System with and without Trocars [16521], Needle Free Connectors [18066]**
der Klasse: / of class: / de la classe: / di classe:	**IIa**

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC / selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". /

meets the provisions of the directive 93/42/EEC 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 93/42/CEE 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 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

ormitätsbewertungsverfahren: /	**Richtlinie 93/42/EWG Anhang V**
nformity assessment procedure: /	**Directive 93/42/EEC Annex V**
rocédure d'évaluation de la conformité: /	**Directive 93/42/CEE Annexe V**
Procedura di valutazione della conformità:	**Direttiva 93/42/CEE senza Allegato V**
Registrier-Nr.: /	**DD 2063008-1**
Registration No.: /	
N°d'enregistrement: /	
Numero di registrazione:	
Benannte Stelle: /	**TÜV Rheinland LGA Products GmbH**
Notified Body: /	**Tillystraße 2**
Organisme notifié: /	**90431 Nürnberg**
Organismo notificato:	**Deutschland**
	CE 0197

Suzhou, 2020.11.18

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

General Manager

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