

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

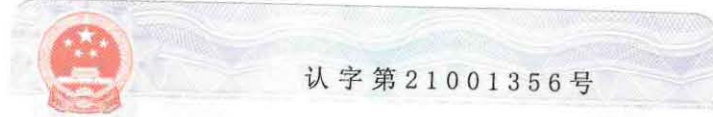
授权签字:

Authorized
Signature:

Zou Ruirui

日期: 2021年01月15日

(Date: Jan. 15, 2021)



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



CE DE
DÉCLARATION DE
G-KONFORMITÄT SERIK

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Name r
Nar

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: / **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:

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

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: / **Nasal Oxygen Cannulae [12700], Suction Catheters [17795],**
the medical device: / **Stomach Tubes [14230], Feeding Tubes [14199], Suction**
le dispositif médical: / **Connecting Tubes with Yankauer [14188,16883], Sterile Latex**
il dispositivo medico: **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: / **IIa**
of class: /
de la classe: /
di classe:

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.



Conformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Richtlinie 93/42/EWG Anhang V
Directive 93/42/EEC Annex V
Directive 93/42/CEE Annexe V
Direttiva 93/42/CEE senza Allegato V

Registrier-Nr.: /
Registration No.: /
N° d'enregistrement: /
Numero di registrazione:

DD 2063008-1

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

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
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

