证明书

CERTIFICATE



中国国际贸易促进委员会 中国国际商会

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

中国国际贸易促进委员会



中国国际商会

China Council for the Promotion of International Trade
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证明书

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号码 No. 243200B0/H06626

兹证明: 在所附企业/公司声明上的南通康锦辰医疗器械有限公司的印章属实。

THIS IS TO CERTIFY THAT: the seal of NANTONG KANGJINCHEN MEDICAL EQUIPMENT CO., LTD. on the annexed ENTERPRISE/COMPANY STATEMENT is genuine.



China Council for the Promotion of International Trade

签证员

Authorized Official:

Jiang Liuyang

日期: 2024年08月15日 (Date: Aug. 15, 2024)

查询网址 Website for verifying the certificate: http://www.rzccpit.com/validate.html

Certificate of EU Medical Device Notification



This is to certify that, according to Regulation 2017/745 - medical devices,

Rep Europe GmbH

Address: Annastr. 9 B, 64347 Griesheim, Germany

has fulfilled all notification responsibility and duty as the European Authorized representative of

Manufacturer: Nantong Kangjinchen Medical Equipment Co., Ltd.

Address: No 10, Zhennan Road, Jiang'an Town, Rugao City, Nantong City, Jiangsu Province,

226000, China

The manufacturer has provided with all the appropriate declaration according the Regulation 2017/745 - medical devices requirements including the EC Declaration of Conformity confirming that the medical devices, as stipulated here below(please see next page), is fulfilling the applicable requirements of Regulation 2017/745.

Where then manufacturer affixes the CE marking to the product listed, they must ensure that all the requirements of the appropriate EU regulation(s) have and continue to be met.

The notification of aforementioned device(s) has been completed by European Authorized representative in Germany, the German Competent Authority has notified the manufacturer's medical device above and has allocated registration.

Rep Europe G

22/Mar./2024

Email: info@rep-europe.de

www.rep-europe.de

No.: MDN-20240322-01



| Product I: | Nebulizer Mask |
|----------------------|---|
| Registration number: | DE/CA23/00200435 |
| Models: | XL/L/M/S |
| Product II: | Oxygen Mask |
| Registration number: | DE/CA23/00200437 |
| Models: | XL/L/M/S, Silicone Mask, Anesthesia Mask, Venturi Mask, Non-Rebreathing |
| | Mask |
| Product III: | Nasal Oxygen Cannula |
| Registration number: | DE/CA23/00200439 |
| Models: | XL/L/M/S, 1.Suction Connecting Tube with Yankauer Handle |
| Product IV: | Oxygen Humidifier (Bubble Humidifier Jar) |
| Registration number: | DE/CA23/00198884 |
| Models: | 250ml, 500ml |
| Product V: | Aerochamber with Mask (Spacer for Aerosol) |
| Registration number: | DE/CA23/00200443 |
| Models: | Adult /Child /Infant |
| Product VI: | Spirometer (Lung Excerciser) |
| Registration number: | DE/CA23/00200454 |
| Models: | 600/900/1200ml; 1.Manual Resuscitator |
| Product VII: | Non-rebreathing Mask |
| Registration number: | DE/CA23/00200456 |
| Models: | XL/L/M/S |
| Product VIII: | Dry Powder Inhalers |
| Registration number: | DE/CA23/00198820 |
| Models: | |
| widueis. | * europe |





本附加证明书仅证明公文书上的签名、签署人签名时的身份,需要时 可证明公文书上的印鉴属实,附加证明书不对公文书内容予以证明。 This Apostille only certifies the authenticity of the signature, the capacity of the person who has signed the public document and, where appropriate,



附加证明书 **APOSTILLE**

(1961年10月5日海牙公约) (Convention de La Haye du 5 octobre 1961)

1. 文书出具国: 中华人民共和国 Country: People's Republic of China

本公文书 This public document

2. 签署人 has been 蒋柳炀 Jiang Liuyang

signed by

签证员

3. 签署人身份 acting in the capacity of

Authorized Official

4. 印鉴名称 bears the seal/stamp of 中国国际贸易促进委员会(16)

China Council for the Promotion of International Trade(16)

证明 Certified

5. 签发地 南京 at

Nanjing

6. 签发日期 2024年08月16日 August 16,2024

7. 签发人 张君/Zhang Jun by 江苏省外事办公室

Foreign Affairs Office of Jiangsu Province

8. 附加证明书编号 认字第243200084973号

9. 签发机关印鉴:

Seal/Stamp:

10. 签名: Signature:



加田年志