



兹证明

上海泽翳工贸有限公司

统一社会信用代码: 91310115572664240N

经营地址: 上海市浦东新区康意路 406 号 4 幢 303 室

注册地址: 上海市浦东新区康意路 406 号 4 幢 303 室

的质量管理体系适用于

医疗器械及其配套产品的销售 (涉及许可要求的产品, 限许可资质范围内, 明细见附件)

已经 NQA 根据标准

ISO 13485: 2016

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系, 并由 NQA 进行监督。获证组织必须定期接受监督审核并经审核合格, 此证书方继续有效。

本证书信息可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询
SNQA 查询网站: www.snqa.com.cn

Managing Director



Certificate Number

47579

Date:

14 April 2020

Valid Until:

14 April 2023

EAC Code:

34/29





This is to certify that the Quality Management System of
Shanghai ZOGEAR Industries Co., Ltd.

Unified Social Credit Code : 91310115572664240N

Operation Address : Room 303, Building 4, No.406, Kangyi Road, Pudong New District, Shanghai, China

Registered Address : Room 303, Building 4, No.406, Kangyi Road, Pudong New District, Shanghai, China

applicable to

Sales of medical devices and related products(products related to licensing requirements, within the scope of the license qualification, see the attachment for details)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website : www.snqa.com.cn

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上海泽翳工贸有限公司
附件

1. 根管锉
2. 根管扩大针
3. 牙科输送机
4. 根管充填器
5. 牙科机用根管锉
6. 牙胶尖
7. 吸潮纸尖
8. 玻璃离子水门汀
9. 聚羧酸锌水门汀
10. 齿科氧化锌丁香酚水门汀
11. 磷酸锌水门汀
12. 金刚砂车针
13. 陶瓷抛光器
14. 高速蜗轮牙钻手机
15. 低速蜗轮牙钻手机
16. 牙科综合治疗机
17. 无菌手术刀片
18. 带线缝合针
19. 超声洁牙机

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Shanghai ZOGEAR Industries Co., Ltd.
Annex

1. Root Canal Instruments
2. Root Canal Reamers
3. Dental Paste Carriers
4. Root Canal Filling
5. Root Canal Files for Engine Use
6. Gutta Percha Points
7. Sterile Absorbent Paper Points
8. Glass Ionomer Cement
9. Zinc Poly-carboxylate Cement
10. Eugenol Cement
11. Zinc-Phosphate Cement
12. Diamond Burs
13. Ceramic Grinders
14. High Speed Air Turbine Dental Handpieces
15. Low Speed Dental Handpieces
16. Dental Units
17. Sterile Surgical Blades
18. Sterile Suture Needles with Thread
19. Ultrasonic Scalers

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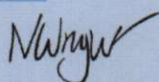




上海泽翳工贸有限公司

附件

- 20. 正畸托槽
- 21. 正畸带环
- 22. 正畸丝
- 23. 正畸粘结剂
- 24. 医用脱脂棉卷
- 25. 医用纱布敷料
- 26. 医用棉签
- 27. 脱脂棉球
- 28. 一次性使用手术衣
- 29. 一次性医用口罩
- 30. 医用外科口罩
- 31. 一次性使用帽子
- 32. 橡胶抛光器
- 33. 一次性使用冲洗管
- 34. 一次性使用手术包
- 35. 一次性使用口腔器械盒
- 36. 涂药棒
- 37. 无纺布片
- 38. 牙科纸围巾


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Annex

- 20. Orthodontic Brackets
- 21. Orthodontic Bands
- 22. Orthodontic Wires
- 23. Orthodontic Adhesives
- 24. Sterile Dental Cotton Rolls
- 25. Sterile Gauze Sponges
- 26. Sterile Cotton Tip Applicators
- 27. Sterile Cotton Ball
- 28. Non-woven Surgical Gowns
- 29. Disposable Medical Face Masks
- 30. Medical Surgical Masks
- 31. Disposable Caps
- 32. Rubber Polishers
- 33. Irrigation Sets
- 34. Disposable Surgical Packs
- 35. Disposable Dental Kits
- 36. Micro Applicator
- 37. Non-woven Sponges
- 38. Dental Bibs

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