

Certificate CN14/30418

**SGS**

The management system of

# Chengdu OCI Medical Devices Co., Ltd.

No. 2401, West Port Avenue, Southwest Airport Economic Development Zone, Shuangliu District, Chengdu, Sichuan Province, 610299, P.R. China

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

Design and Manufacture of Sterile Polyethersulfone Hollow Fiber Hemodialyzer, Sterile Hemodialysis Blood Tubing Sets and Sterile Arteriovenous Fistula Needle Sets

This certificate is valid from 24 March 2023 until 02 April 2026 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 02 April 2014

*Jonathan U. Hall*

Authorised by  
Jonathan Hall  
Global Head - Certification Services

SGS United Kingdom Ltd  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
t +44 (0)151 350-6666 - www.sgs.com



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



Certificado CN14/30418

El Sistema de administración de

**Chengdu OCI Medical Devices Co., Ltd.**

No. 2401, West Port Avenue, Southwest Airport Economic Development zone, Shuangliu District, Chengdu, Sichuan Province, 610299 P.R. China

ha sido evaluado y certificado en cuanto al cumplimiento de los requisitos de

**ISO 13485:2016**

**EN ISO 13485:2016**

para las siguientes actividades

**Diseño y Fabricación de Dispositivos de Hemodializador de Fibra Hueca de Polietersulfona Estéril, Juegos de Tubos de Sangre de Hemodiálisis Estériles y Juegos de Aguja Estériles para Fístula Arteriovenosa.**

Este certificado es válido desde el 24 de marzo de 2023 hasta el 02 de abril de 2026, sigue válido sujeto a auditorías de vigilancia satisfactorias.

Emitido 6 certificados desde el 02 de abril de 2014 autorizado por

(Firma)



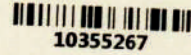
SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44(0)151 350-6666 [www.sgs.com](http://www.sgs.com)

Este documento es un certificado electrónico auténtico solo para el uso del propósito de Cliente. Se permite versión impresa del certificado electrónico y se considerará como una copia. Este documento ha sido emitido por la Compañía sujeto a las Condiciones Generales de servicios de certificación de SGS disponibles en TERMS AND CONDITIONS I SGS. Se ha puesto la atención sobre las limitaciones de responsabilidad, indemnización y cuestiones jurisdiccionales establecidas en el mismo. El documento está con la protección de copyright y cualquiera alteración y falsificación no autorizada del contenido o apariencia de este documento es ilegal.

Classified as Public



本附加证明书仅证明公文文书上的签名、签署人签名时的身份, 需要时可证明公文文书上的印章属实, 附加证明书不对公文文书内容予以证明。  
 This Apostille only certifies the authenticity of the signature, the capacity of the person who has signed the public document and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued.  
 Visit <https://consular.mfa.gov.cn/VERIFY/> and scan the QR code to verify the issuance of this Apostille.



10355267



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 signed by 高丽超  
Gao Lichao

3. 签署人身份  
acting in the capacity of 签证员  
Authorized Official

4. 印鉴名称  
bears the seal/stamp of 中国国际贸易促进委员会  
China Council for the Promotion of International Trade

证明 Certified

5. 签发地  
at 北京  
Beijing

6. 签发日期  
the 2024年03月06日  
March 06, 2024

7. 签发人  
by 芦君玲, 一等秘书/ Lu Junling, First Secretary  
外交部领事司  
Department of Consular Affairs of the Ministry of Foreign Affairs



8. 附加证明书编号  
No 认字第240000071332号

9. 签发机关印鉴:  
Seal/Stamp:



10. 签名:  
Signature:

芦君玲